
An Overview of the Medicare Part D Prescription Drug Benefit

Published: Nov 13, 2019



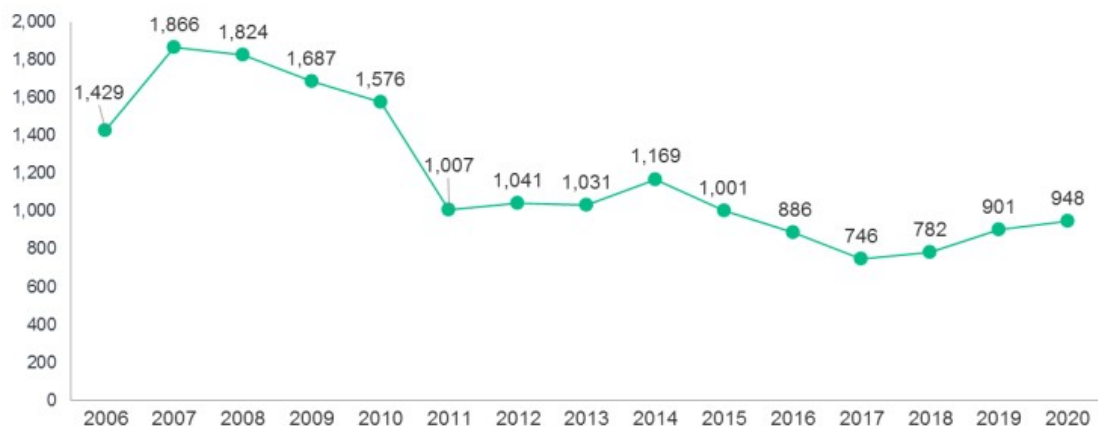
Medicare Part D is a voluntary outpatient prescription drug benefit for people with Medicare, provided through private plans approved by the federal government. Beneficiaries can choose to enroll in either a stand-alone prescription drug plan (PDP) to supplement traditional Medicare or a Medicare Advantage (<https://www.kff.org/medicare/fact-sheet/medicare-advantage/>) prescription drug plan (MA-PD), mainly HMOs and PPOs, that cover all Medicare benefits including drugs. In 2019, 45 million (<https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/>) of the more than 60 million people covered by Medicare are enrolled in Part D plans. Of this total, more than half (56%) are enrolled in stand-alone PDPs and more than 4 in 10 (44%) are enrolled in Medicare Advantage drug plans. This fact sheet provides an overview of the Medicare Part D program, plan availability, enrollment, and spending and financing, based on data from the Centers for Medicare & Medicaid Services (CMS), the Congressional Budget Office (CBO), and other sources.

Medicare Prescription Drug Plan Availability in 2020

In 2020, 948 PDPs will be offered across the 34 PDP regions nationwide (excluding the territories). This represents an increase of 47 PDPs from 2019 (a 5% increase) and the third year in a row with more stand-alone PDPs, after three years of plan reductions (Figure 1).

Figure 1

A Total of 948 Medicare Part D Stand-Alone Prescription Drug Plans Will Be Offered in 2020, a 5% Increase from 2019



NOTES: PDP is prescription drug plan. Excludes PDPs in the territories (n=11 in 2020).
SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2006-2020 PDP landscape source files.



Figure 1: A Total of 948 Medicare Part D Stand-Alone Prescription Drug Plans Will Be Offered in 2020, a 5% Increase from 2019

The relatively large increase in the number of PDPs since 2018 is likely due to the elimination by CMS of the “meaningful difference” requirement (<https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program>) for enhanced benefit PDPs offered by the same organization in the same region. Plans with enhanced benefits can offer a lower deductible, reduced cost sharing, and/or a higher initial coverage limit. Previously, PDP sponsors were required to demonstrate that their enhanced PDPs were meaningfully different in terms of enrollee out-of-pocket costs in order to ensure that plan offerings were more distinct. Between 2018 and 2020, the number of enhanced PDPs has increased from 421 to 566, largely due to this policy change.

Beneficiaries in each state will have a choice of multiple stand-alone PDPs in 2020, ranging from 24 PDPs in Alaska to 32 PDPs in California (*see map*). In addition, beneficiaries will be able to choose among multiple MA-PDs offered at the local level for coverage of their Medicare benefits.

Medicare Part D Stand-alone Prescription Drug Plans in 2020

(<https://www.kff.org/wp->




24 - 26

27 - 28

29 - 30

31 - 32

Roll
over a state to show
information

State	Number of Stand-alone Prescriptio...
United States	948
Alabama	30
Alaska	24
Arizona	31
Arkansas	27
California	32
Colorado	26
Connecticut	25
Delaware	27
District of Columbia	27
Show 10 rows 	

Low-Income Subsidy Plan Availability in 2020

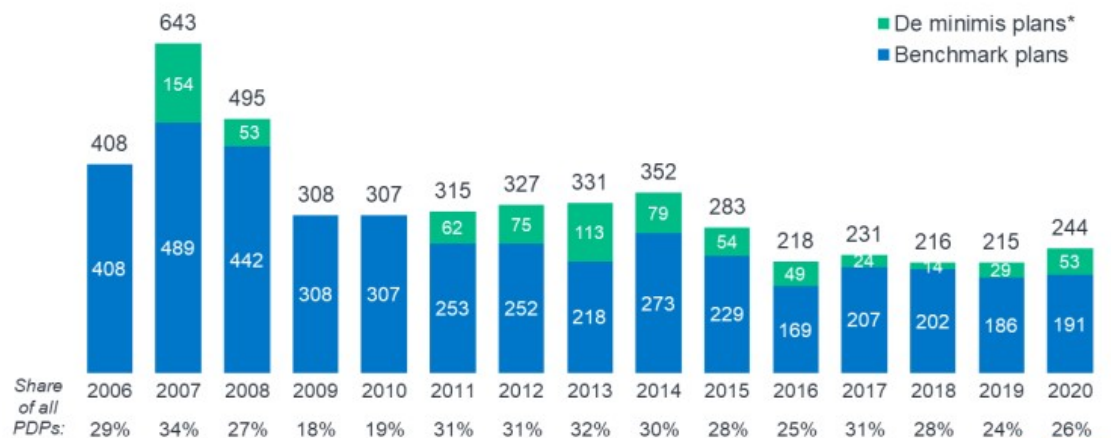
Beneficiaries with low incomes and modest assets are eligible for assistance with Part D plan premiums and cost sharing. Through the Part D Low-Income Subsidy (LIS) program, additional premium and cost-sharing assistance is available for Part D enrollees with low incomes (less than 150% of poverty, or \$18,735 for individuals/\$25,365 for married couples in 2019) and modest assets (less than \$14,390 for individuals/\$28,720 for couples in 2019).

In 2020, 244 plans will be available for enrollment of LIS beneficiaries for no premium, 29 more than in 2019 (a 13% increase), and the first year with a relatively substantial increase in the number of benchmark plans since 2017 (Figure 2). Just over one-fourth of PDPs in 2020 (26%) are benchmark plans.

All LIS enrollees can select any plan offered in their area, but if they are enrolled in a non-benchmark plan, they may be required to pay some portion of their plan's monthly premium. Some enrollees have fewer benchmark plan options than others, since benchmark plan availability varies at the Part D region level. The number of premium-free PDPs in 2020 ranges from a low of 2 plans in Ohio to 12 plans in Arizona (*see map*).

Figure 2

In 2020, 244 Part D Stand-Alone Drug Plans Will Be Available Without a Premium to Enrollees Receiving the Low-Income Subsidy ("Benchmark" Plans)



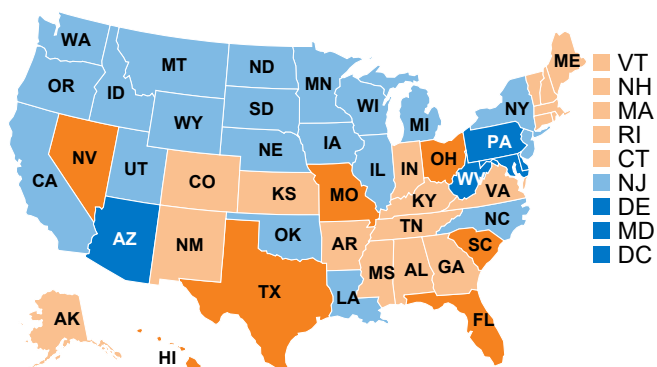
NOTES: PDP is prescription drug plan. *De minimis plans can retain Low-Income Subsidy beneficiaries despite exceeding the benchmark premium by a minimal amount (up to \$2 in 2020).

SOURCE: KFF analysis of Centers for Medicare & Medicaid Services 2006-2020 Part D plan files.



Figure 2: In 2020, 244 Part D Stand-Alone Drug Plans Will Be Available Without a Premium to Enrollees Receiving the Low-Income Subsidy ("Benchmark" Plans)

Medicare Part D Benchmark Plans in 2020



No State Selected

Roll
over a state to show
information

State	Number of Benchmark PDPs
United States	244
Alabama	7
Alaska	7
Arizona	12
Arkansas	6
California	8
Colorado	7
Connecticut	7
Delaware	10
District of Columbia	10

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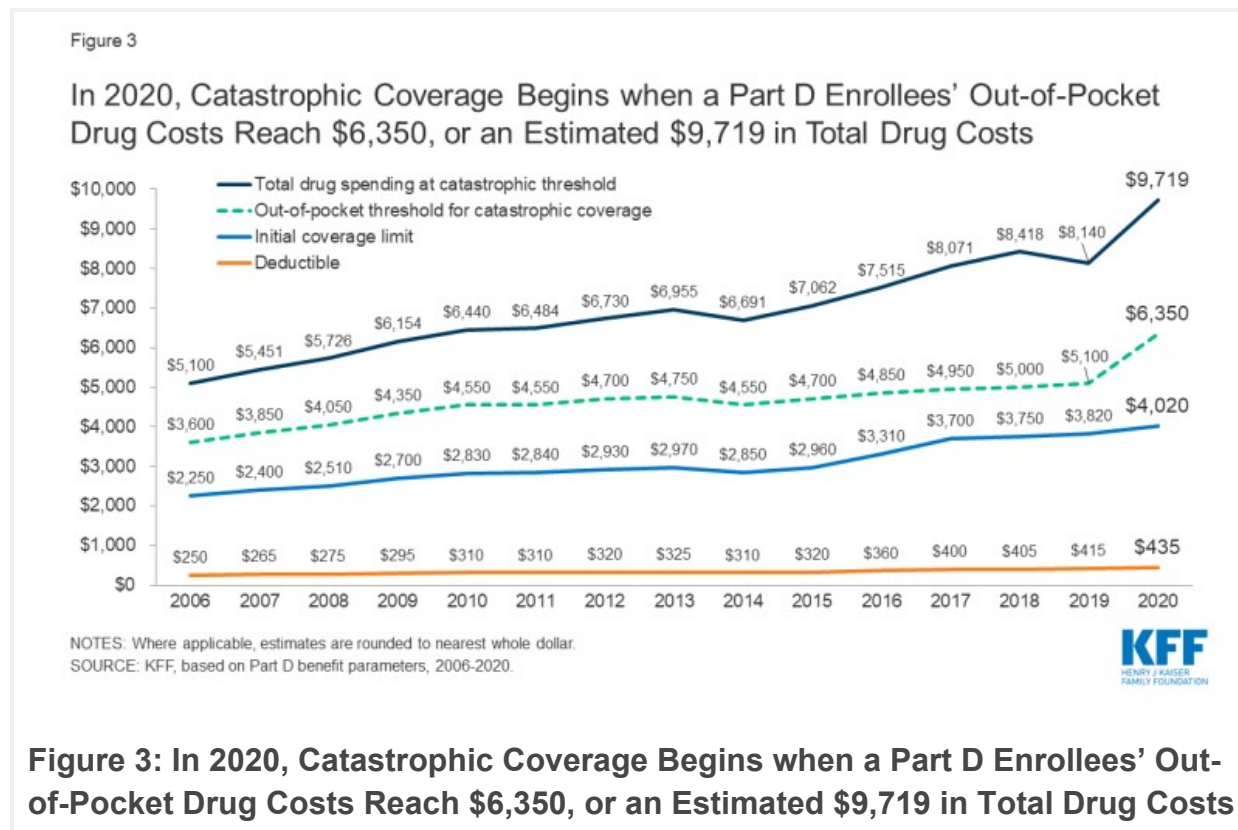
Part D Plan Premiums and Benefits in 2020

Premiums

The 2020 Part D base beneficiary premium—which is based on bids submitted by both PDPs and MA-PDs—is **\$32.74** (<https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDandMABenchmarks2020.pdf>), a modest (1%) reduction from 2019. But actual premiums paid by Part D enrollees vary considerably from this amount. For 2020, PDP monthly premiums vary by plan across the country (and even within regions), ranging from a low of \$12.18 for a PDP available in California to a high of \$191.40 for a PDP in South Carolina. In addition to the monthly premium, Part D enrollees with higher incomes (\$87,000/individual; \$174,000/couple) pay an income-related premium surcharge, ranging from \$12.20 to \$76.40 per month in 2020 (depending on income).

Benefits

The Part D defined standard benefit has several phases where cost sharing for enrollees varies, including a deductible, an initial coverage phase, a coverage gap phase, and catastrophic coverage. The standard benefit amounts are indexed to change annually based on the rate of Part D per capita spending growth, and, with the exception of 2014, have increased each year since 2006 (Figure 3).

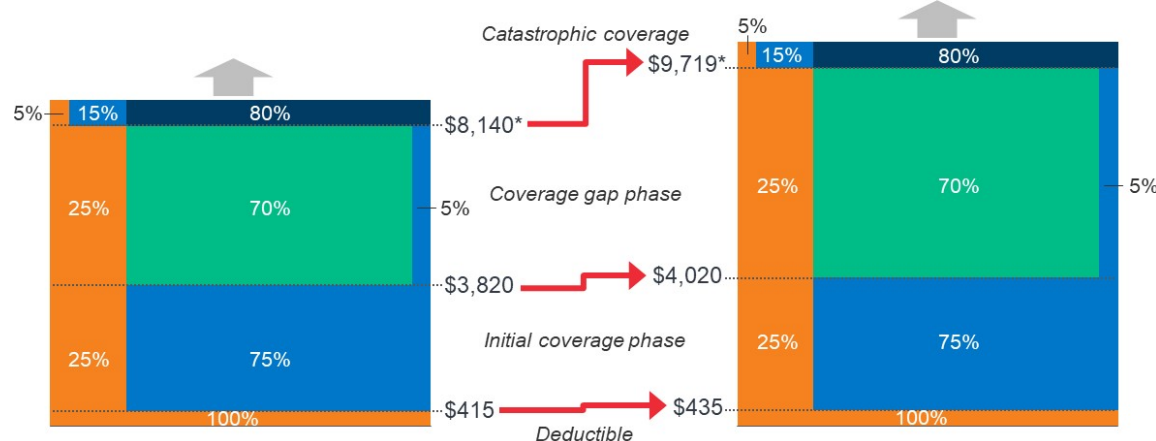


In 2020, Medicare Part D enrollees are facing a relatively large increase in out-of-pocket drug costs before they qualify for catastrophic coverage (Figure 4). This is due to the expiration of the ACA provision that constrained the growth in out-of-pocket costs for Part D enrollees by slowing the growth rate in the catastrophic threshold between 2014 and 2019. For 2020, the out-of-pocket spending threshold will increase by \$1,250, from \$5,100 to \$6,350.

Figure 4

Medicare Part D Standard Benefit Parameters Will Increase in 2020

Share of costs paid by: ■ Plans ■ Enrollees ■ Manufacturers ■ Medicare



NOTES: Some amounts rounded to nearest dollar. Share of costs in coverage gap reflect costs for brand-name drugs in 2019, and both brands and generics in 2020. *Corresponds to an out-of-pocket threshold for catastrophic coverage of \$5,100 in 2019 and \$6,350 in 2020.

SOURCE: KFF, based on 2019 and 2020 Part D benefit parameters.



Figure 4: Medicare Part D Standard Benefit Parameters Will Increase in 2020

Part D enrollees will also face higher out-of-pocket costs in 2020 for the deductible and in the initial coverage phase, as they have in prior years. The standard deductible is increasing from \$415 in 2019 to \$435 in 2020, while the initial coverage limit is increasing from \$3,820 in 2019 to \$4,020 in 2020. For costs in the coverage gap phase, beneficiaries will pay 25% for both brand-name and generic drugs, with plans paying the remaining 75% of generic drug costs—which means that, effective in 2020, the Part D coverage gap will be fully phased out. For total drug costs above the catastrophic threshold, Medicare pays 80%, plans pay 15%, and enrollees pay either 5% of total drug costs or \$3.60/\$8.95 for each generic and brand-name drug, respectively.

Part D plans must offer either the defined standard benefit or an alternative equal in value (“actuarially equivalent”), and can also provide enhanced benefits. Both basic and enhanced benefit plans vary in terms of their specific benefit design, coverage, and costs, including deductibles, cost-sharing amounts, utilization management tools (i.e., prior authorization, quantity limits, and step therapy), and formularies (i.e., covered drugs). Plan formularies must include drug classes covering all disease states, and a minimum of two chemically distinct drugs in each class. Part D plans are required to cover all drugs in six so-called “protected” classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.

Part D and Low-Income Subsidy Enrollment

Enrollment in Medicare Part D plans is voluntary, with the exception of beneficiaries who are eligible for both Medicare and Medicaid and certain other low-income beneficiaries who are automatically enrolled in a PDP if they do not choose a plan on their own. Unless beneficiaries have drug coverage from another source that is at least as good as standard Part D coverage (“creditable coverage”), they face a penalty equal to 1% of the national average premium for each month they delay enrollment.

In 2019, 45 million Medicare beneficiaries are enrolled in Medicare Part D plans, including employer-only group plans. Another 1.4 million beneficiaries (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf#page=144><https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>) are estimated to have drug coverage through employer-sponsored retiree plans where the employer receives subsidies equal to 28% of drug expenses between \$435 and \$8,950 per retiree (in 2020). Several million beneficiaries are estimated to have other sources of drug coverage, including employer plans for active workers, FEHBP, TRICARE, and Veterans Affairs (VA). Yet 12% of people with Medicare (http://www.medpac.gov/docs/default-source/data-book/jun19_databook_sec10_sec.pdf#page=11) are estimated to lack creditable drug coverage.

An estimated 13 million (<https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/>) Part D enrollees receive the Low-Income Subsidy in 2019. Beneficiaries who are dually eligible, QMBs, SLMBs, QIs, and SSI-onlys automatically qualify for the additional assistance, and Medicare automatically enrolls them into PDPs with premiums at or below the regional average (the Low-Income Subsidy benchmark) if they do not choose a plan on their own. Other beneficiaries are subject to both an income and asset test and need to apply for the Low-Income Subsidy through either the Social Security Administration or Medicaid.

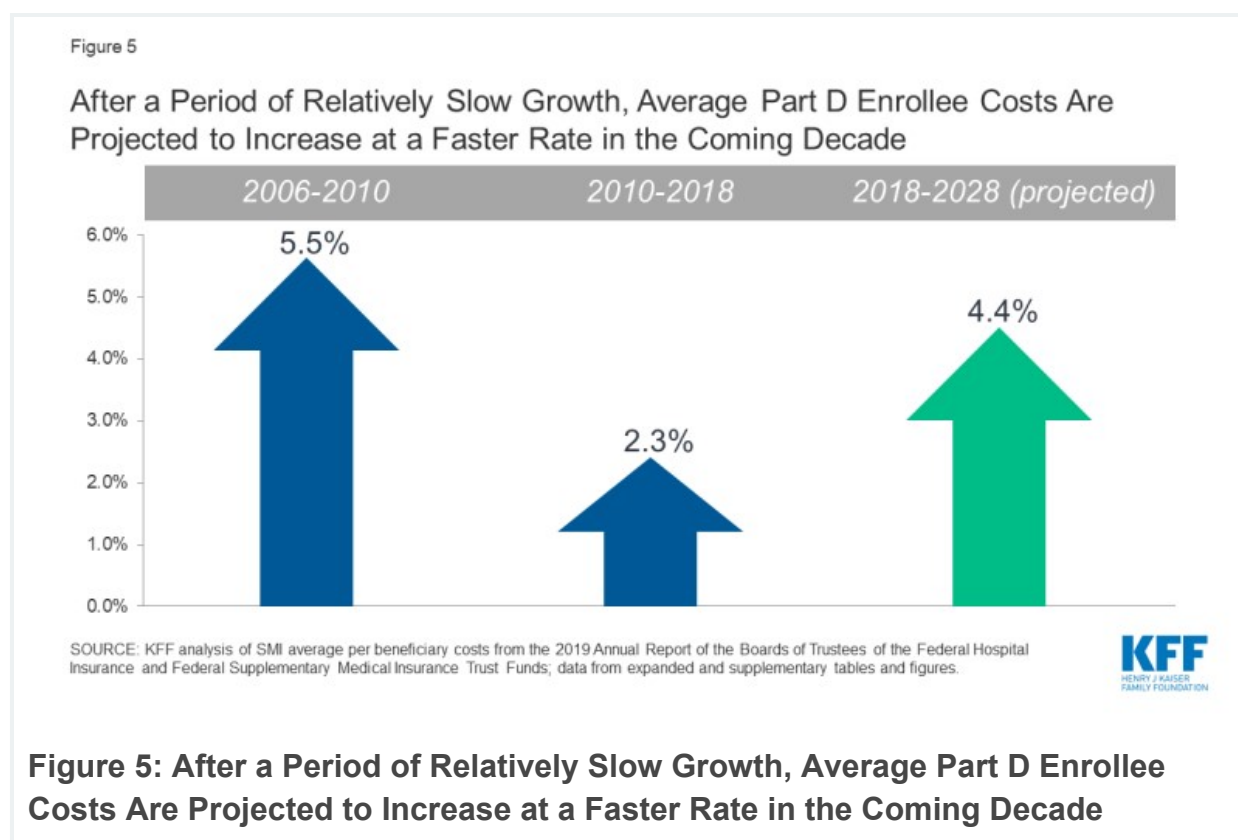
Part D Spending and Financing

Part D Spending

The Congressional Budget Office (CBO) estimates that spending on Part D benefits will total \$88 billion in 2020 (https://www.cbo.gov/system/files/2019-05/51302-2019-05-medicare_0.pdf), representing 13% of net Medicare outlays (net of offsetting receipts from premiums and state transfers). Part D spending depends on several factors, including the number of Part D enrollees, their health status and drug use, the number of enrollees receiving the Low-Income Subsidy, and plans’ ability to negotiate discounts (rebates) with drug companies and preferred pricing arrangements with pharmacies, and manage use (e.g., promoting use of generic drugs, prior authorization, step therapy, quantity limits, and mail order). Federal law currently prohibits the Secretary of Health and Human

Services from interfering in drug price negotiations (<https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/>) between Part D plan sponsors and drug manufacturers.

The average annual growth rate in per beneficiary costs for Part D is projected to be higher in the coming decade (4.4%) than it was between 2010 and 2018 (2.3%) (Figure 5). This is due in part to higher Part D program costs associated with an increase in the use and availability of expensive specialty drugs, which is expected to be reflected in higher reinsurance payments from Medicare to plans (described below). Part D benefits spending is projected to increase modestly from 13% of total (net) Medicare spending in 2020 to 15% in 2029, based on CBO projections (https://www.cbo.gov/system/files/2019-05/51302-2019-05-medicare_0.pdf).



Part D Financing

Financing for Part D (<http://kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/>) comes from general revenues (71%), beneficiary premiums (17%), and state contributions (12%). The monthly premium paid by enrollees is set to cover 25.5% of the cost of standard drug coverage. Medicare subsidizes the remaining 74.5%, based on bids submitted by plans for their expected benefit payments. Higher-income Part D enrollees pay a larger share of standard Part D costs, ranging from 35% to 85%, depending on income.

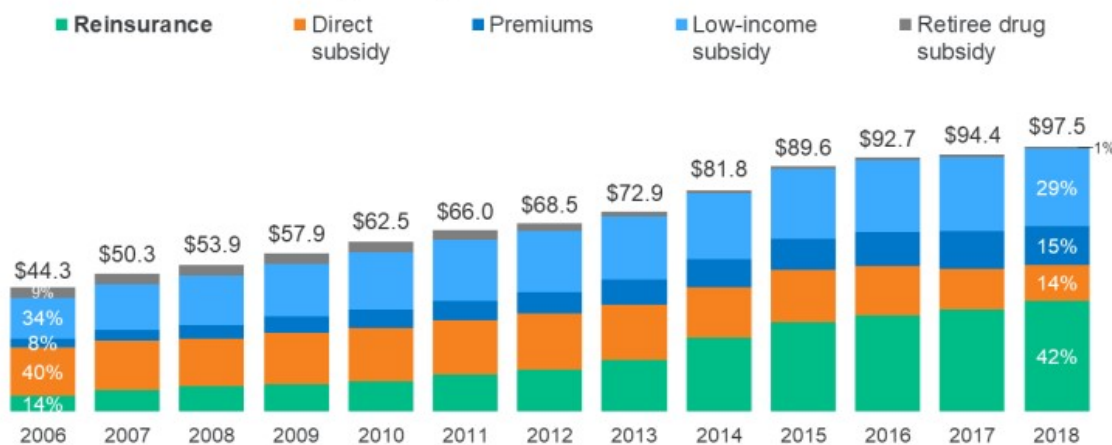
Payments to Plans

For 2020, Medicare's actuaries estimate (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf#page=148>) that Part D plans will receive direct subsidy payments averaging \$259 per enrollee overall and \$2,531 for enrollees receiving the LIS; employers are expected to receive, on average, \$592 for retirees in employer-subsidy plans. Part D plans' potential total losses or gains are limited by risk-sharing arrangements with the federal government ("risk corridors"). Plans also receive additional risk-adjusted payments based on the health status of their enrollees and reinsurance payments for very high-cost enrollees.

Under reinsurance, Medicare subsidizes 80% of total drug spending incurred by Part D enrollees above the catastrophic coverage threshold. For 2020, average reinsurance payments per enrollee are estimated to be \$955. In the aggregate, Medicare's reinsurance payments to plans have grown from \$6 billion in 2006 to an estimated \$43 billion in 2019 (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf#page=149>), accounting for a larger share of total Part D spending over time, from 14% in 2006 to 42% in 2018 (Figure 6). Higher benefit spending above the catastrophic threshold is a result of several factors, including an increase in the number of high-cost drugs, prescription drug price increases, and a change made by the ACA to count the manufacturer discount on the price of brand-name drugs in the coverage gap towards the out-of-pocket threshold for catastrophic coverage; this change has led to more Part D enrollees with spending above the catastrophic threshold over time.

Figure 6

Spending for Catastrophic Coverage (“Reinsurance”) Has Increased as a Share of Total Medicare Part D Spending, from 14% in 2006 to 42% In 2018



SOURCE: 2016-2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Table IV.B10.



Figure 6: Spending for Catastrophic Coverage (“Reinsurance”) Has Increased as a Share of Total Medicare Part D Spending, from 14% in 2006 to 42% In 2018

Issues for the Future

The Medicare drug benefit has helped to reduce out-of-pocket drug spending for enrollees, which is especially important to those with modest incomes or very high drug costs. But with drug prices on the rise, more plans charging coinsurance rather than flat copayments for covered brand-name drugs, and an increase in the annual out-of-pocket threshold for 2020, Part D enrollees can expect to face higher out-of-pocket costs for their medications.

In light of ongoing attention to prescription drug spending and higher drug prices, the Trump Administration and members of Congress have issued several proposals (<https://www.kff.org/medicare/issue-brief/a-look-at-recent-proposals-to-control-drug-spending-by-medicare-and-its-beneficiaries/>) to control drug spending by Medicare and beneficiaries. Several of these proposals address concerns about the lack of a hard cap on out-of-pocket spending for Part D enrollees, the significant increase in Medicare spending for enrollees with high drug costs, and the relatively weak financial incentives faced by Part D plan sponsors to control high drug costs. Such proposals include allowing Medicare to negotiate the price of drugs, requiring manufacturers to pay a rebate to the federal government if their drug prices increase faster than inflation, using drug prices in other countries in determining pricing for drugs in the U.S., and shifting more of the responsibility for catastrophic coverage costs to Part D plans and drug manufacturers.

Whether or not any of these proposed changes are adopted, understanding how well Part D continues to meet the needs of people on Medicare will be informed by ongoing monitoring of the Part D plan marketplace, formulary coverage and costs for new and existing medications, and Medicare beneficiaries' out-of-pocket drug spending.

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From: [REDACTED]
 To: [REDACTED]
 Cc: [REDACTED]
 Subject: RE: Partial Subsidy
 Date: Monday, August 24, 2020 3:31:19 PM

Hi [REDACTED],

Here are the enrollment counts and %s based on public data. Please let us know if you have questions.
 Thanks!

	March 2018	March 2019	March 2020
Plan Enrollment - LIS	12,477,989	12,671,249	12,811,991
MAPD	4,852,404	5,399,304	6,090,896
PDP	7,625,585	7,271,945	6,721,095
Total Part D Enrollment	43,859,625	45,445,000	47,023,873
MAPD	18,452,877	19,960,506	21,945,287
PDP	25,406,748	25,484,494	25,078,586
% of Part D Enrollment with LIS	28.4%	27.9%	27.2%

Data source: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/LIS-Enrollment-by-Plan>

*Counts and percentages are calculated based on plan enrollments greater than 10.

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Gender	Percentage
Men	85%
Women	80%

Category	Percentage
Current administration	~80%
Previous administrations	~20%

[illegible]

Administration	Percentage
Current Administration	85%
Previous Administration	15%

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Age Group	Should Take Action (%)	Should Not Take Action (%)
18-29	85	15
30-49	85	15
50-69	85	15
70+	85	15

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Income-to-poverty ratio among Medicare beneficiaries enrolled in Part D plans, 2018.

Income level	All Medicare beneficiaries	Enrolled in Part D at any point in 2018	
		Yes	No
<=100% of the Federal Poverty Level	16.2%	19.3%	5.3%
>100% and <=120% of FPL	5.5%	6.3%	2.7%
>120% and <=135% of FPL	3.8%	4.1%	2.6%
>135% and <=200% of FPL	16.2%	16.8%	13.9%
>200% and <=300% of FPL	17.3%	17.1%	17.9%
>300% and <=500% of FPL	19.2%	17.3%	26.0%
>500% and <=800% of FPL	12.8%	11.3%	18.1%
>800% of FPL	9.0%	7.7%	13.5%
Total	100%	100%	100%

All percentages are column percentages.

Source data: Medicare Current Beneficiary Survey, 2018 Survey File.

Unweighted n = 15,237 (n = 12,554 with Part D, 2,683 without Part D).

Part D includes Medicare Advantage Prescription Drug plans.

Includes all age groups of Medicare beneficiaries, and both community- and facility-dwelling beneficiaries.

Weighted to represent the national population of Medicare beneficiaries enrolled in Medicare at any point in 2018 (weighted n = 60,926,261).

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Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid Cardiomyopathy

Editorial, see p 1225

BACKGROUND: In patients with transthyretin amyloid cardiomyopathy, tafamidis reduces all-cause mortality and cardiovascular hospitalizations and slows decline in quality of life compared with placebo. In May 2019, tafamidis received expedited approval from the US Food and Drug Administration as a breakthrough drug for a rare disease. However, at \$225 000 per year, it is the most expensive cardiovascular drug ever launched in the United States, and its long-term cost-effectiveness and budget impact are uncertain. We therefore aimed to estimate the cost-effectiveness of tafamidis and its potential effect on US health care spending.

METHODS: We developed a Markov model of patients with wild-type or variant transthyretin amyloid cardiomyopathy and heart failure (mean age, 74.5 years) using inputs from the ATTR-ACT trial (Transthyretin Amyloidosis Cardiomyopathy Clinical Trial), published literature, US Food and Drug Administration review documents, healthcare claims, and national survey data. We compared no disease-specific treatment ("usual care") with tafamidis therapy. The model reproduced 30-month survival, quality of life, and cardiovascular hospitalization rates observed in ATTR-ACT; future projections used a parametric survival model in the control arm, with constant hazards reduction in the tafamidis arm. We discounted future costs and quality-adjusted life-years by 3% annually and examined key parameter uncertainty using deterministic and probabilistic sensitivity analyses. The main outcomes were lifetime incremental cost-effectiveness ratio and annual budget impact, assessed from the US healthcare sector perspective. This study was independent of the ATTR-ACT trial sponsor.

RESULTS: Compared with usual care, tafamidis was projected to add 1.29 (95% uncertainty interval, 0.47–1.75) quality-adjusted life-years at an incremental cost of \$1 135 000 (872 000–1 377 000), resulting in an incremental cost-effectiveness ratio of \$880 000 (697 000–1 564 000) per quality-adjusted life-year gained. Assuming a threshold of \$100 000 per quality-adjusted life-year gained and current drug price, tafamidis was cost-effective in 0% of 10 000 probabilistic simulations. A 92.6% price reduction from \$225 000 to \$16 563 would be necessary to make tafamidis cost-effective at \$100 000/quality-adjusted life-year. Results were sensitive to assumptions related to long-term effectiveness of tafamidis. Treating all eligible patients with transthyretin amyloid cardiomyopathy in the United States with tafamidis (n=120 000) was estimated to increase annual healthcare spending by \$32.3 billion.

CONCLUSIONS: Treatment with tafamidis is projected to produce substantial clinical benefit but would greatly exceed conventional cost-effectiveness thresholds at the current US list price. On the basis of recent US experience with high-cost cardiovascular medications, access to and uptake of this effective therapy may be limited unless there is a large reduction in drug costs.

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Clinical Perspective

What Is New?

- In patients with transthyretin amyloid cardiomyopathy, tafamidis reduces all-cause mortality and slows decline in quality of life compared with placebo, but it is the most expensive cardiovascular drug ever launched in the United States.
- In this simulation model of US adults, tafamidis therapy for transthyretin amyloid cardiomyopathy was estimated to cost \$880 000 per quality-adjusted life-year gained compared with usual care and increased annual health care costs by \$32.3 billion (including a 9.3% increase in total spending on all prescription drugs over 2018 levels).
- A 92.6% reduction in drug price from \$225 000 annually to \$16 563 would be necessary to meet a \$100 000 per quality-adjusted life-year threshold.

What Are the Clinical Implications?

- Assuming 2019 prices, tafamidis use does not meet generally accepted cost-effectiveness thresholds and is estimated to increase US health care costs substantially.
- On the basis of recent US experience with high-cost cardiovascular medications, access to and uptake of this potentially life-saving therapy may be limited unless there is a large reduction in drug costs.

Heat failure with preserved ejection fraction (HFpEF) is a heterogeneous clinical syndrome that accounts for approximately 50% of all heart failure and lacks effective treatments. Transthyretin amyloid cardiomyopathy (ATTR-CM), caused by the accumulation in the myocardium of amyloid fibrils composed of misfolded transthyretin, is an underrecognized cause of HFpEF in older adults.¹ In addition to causing heart failure, it increases the risk of conduction abnormalities, atrial fibrillation, embolic stroke, and cardiovascular death, and results in a median survival of 2.5 to 3.5 years from diagnosis if untreated.^{1,2}

Tafamidis is a drug that binds to and stabilizes transthyretin, thereby preventing transthyretin tetramer dissociation, the rate-limiting step in transthyretin amyloid deposition. In the ATTR-ACT trial (Transthyretin Amyloidosis Cardiomyopathy Clinical Trial), patients with ATTR-CM and heart failure who received tafamidis experienced lower all-cause mortality, fewer cardiovascular hospitalizations, and a slower decline in quality of life and functional capacity compared with patients who received placebo.² In May 2019, tafamidis received expedited approval from the US Food and Drug Administration (FDA) as a breakthrough drug, a designation reserved for therapies “intended to treat a serious or life-threatening disease” with preliminary evidence

to suggest “a substantial improvement over existing therapies.”³ However, at a list price of \$225 000 per year, it is the most expensive cardiovascular drug ever launched in the United States, raising concerns about cost-effectiveness, affordability, and access. A timely and rigorous cost-effectiveness evaluation would help inform clinical and policy discussions regarding uptake of tafamidis and may influence drug pricing as the drug enters the market. We therefore aimed to perform an independent cost-effectiveness analysis of tafamidis for ATTR-CM, with the goal of better understanding the potential effects of this high-priced therapy on US healthcare spending.

METHODS

The simulation model and key inputs used to conduct this research are available to interested researchers who submit a 1- to 2-page research proposal and collaboration plan to Dr Kazi, and sign a Creative Commons agreement, pending approval by the model team. Data used to generate the inputs for this study come from health care claims, surveys, and publications detailed in Table 1 and the [Data Supplement](#) and may be requested directly from their primary source. Data on health surveys, vital statistics, and health care costs are publicly available from government sources as described. Because the study relied on publicly available deidentified data, this was deemed to not be human subjects research and institutional review board approval was therefore not required.

Model Structure

We developed a state-transition Markov model of patients with wild-type or variant (ie, hereditary) ATTR-CM and heart failure using inputs from the ATTR-ACT trial, published literature, FDA review documents, national claims data, and the Medical Expenditure Panel Survey.^{2,4,5,9,10,12–17} In monthly cycles, patients could continue to live with heart failure (with declining quality of life related to advancing disease), experience cardiovascular hospitalizations, or die from cardiovascular or noncardiovascular causes (Figure 1). We adopted the United States healthcare sector perspective, including all healthcare-related expenditures regardless of who incurs them, and a lifetime analytic horizon. Future costs and benefits were discounted at 3% per year. We adhered to the guidelines recommended by the Second Panel for Cost-Effectiveness in Health and Medicine.⁶

Target Population

The simulated population reflected the characteristics of patients in ATTR-ACT, a phase 3, multicenter, placebo-controlled, double-blind, randomized trial that enrolled patients between 18 and 90 years of age who had wild-type or variant ATTR-CM, a history of heart failure, and at least 1 previous hospitalization for heart failure or clinical evidence of heart failure.² Patients with New York Heart Association Class IV symptoms, an implanted left ventricular assist device, or severe renal insufficiency (estimated glomerular filtration rate <25 mL/min/m²) were excluded. The mean age at study entry was 74.5 years, and 11% were women.

Table 1. Input Parameters

Parameter	Base-Case Value	Range in Sensitivity Analyses	Distribution for Probabilistic Analyses	Source(s)
Transition probabilities				
Rate of cardiovascular hospitalizations, per person per year	0.70	0.62–0.80	Log-normal	Maurer et al 2018, ² Center for Drug Evaluation and Research 2019 ⁴
Proportion of cardiovascular hospitalizations that are fatal	0.0954	0.035–0.105	Beta	Wadhera 2018, ⁵ range assumed
Rate of death from any cause in the control arm, per person per year	Weibull distribution estimated from control arm of ATTR-ACT, with the following parameters: σ : 0.644 (standard error, 0.1081) κ 3.820 (standard error, 0.0887)		Weibull*	Maurer et al 2018 ²
Discount rate, per year	0.03	0.01–0.08	—	Sanders et al 2016 ⁶
Effectiveness of tafamidis				
Hazard ratio for cardiovascular hospitalizations, compared with usual care	0.68	0.56–0.81	Log-normal	Maurer et al 2018 ²
Rate of death from any cause in the tafamidis arm, per person per year	Months 0-18: Identical to the control arm. Months 18–30: Weibull distribution estimated from pooled tafamidis arm of ATTR-ACT, with the following parameters: σ : 0.939 (standard error, 0.1628) κ : 4.429 (standard error, 0.3116). Months >30: Hazard ratio relative to usual care as observed in month 30 of the simulation		— Weibull* —	Maurer et al 2018 ²
Costs				
Tafamidis therapy, US dollars per year	225 000	2,250–500 000	—	Truven Health Analytics, ⁷ range assumed
Background healthcare cost, by age, US dollars			Normal	Medical Expenditure Panel Survey ⁸
<75 y	19,785	19,050–20,520		
75–85 y	18,462	17,967–18,958		
>85 y	17,417	16,945–17,889		
Cardiovascular hospitalization cost, US dollars			Normal	Healthcare Cost and Utilization Project, ⁹ Peterson et al 2015 ¹⁰
<75 y	20,219	16,256–24,182		
75–85 y	20,219	16,256–24,182		
>85 y	13,716§	11,028–16,404		
Clinic visit, US dollars	148	120–175	Normal	Centers for Medicare and Medicaid Services ¹¹
Quality of life, Kansas City Cardiomyopathy Questionnaire–Overall Score				
Baseline	66.72	62.62–70.82	Normal	Maurer et al 2018 ²
Change in score at 30 months in the control arm	–20.81	–24.67 to 16.95	Normal	Center for Drug Evaluation and Research 2019 ⁴
Change in score at 30 months in the tafamidis arm	–7.16	–9.94 to –4.38	Normal	Center for Drug Evaluation and Research 2019 ⁴

*For the purpose of the probabilistic sensitivity analysis, we assumed that the underlying α and κ parameter estimates of the Weibull survival curve had a bivariate normal distribution.

†The small decline in mean hospitalization costs has been previously described and may relate to lower rates of utilization, on average, of high-cost invasive procedures in adults older than 85 years of age.

Treatment Strategies

We evaluated the effect of tafamidis compared with no disease-specific ATTR-CM treatment ("usual care").

Transition Probabilities for the First 30 Months

The model was calibrated to reproduce 30-month survival, quality-of-life, and cardiovascular hospitalization rates observed in ATTR-ACT, on the basis of published data and

publicly available FDA review documents.^{2,4} In ATTR-ACT, compared with patients receiving placebo, patients receiving tafamidis had lower all-cause mortality at 30 months (hazard ratio, 0.70 [95% CI, 0.56–0.81]) and a lower rate of cardiovascular hospitalizations (relative risk ratio, 0.68 [95% CI, 0.56–0.80]). To estimate survival in both arms, we fit separate parametric Weibull models to the observed survival in the control and intervention arms of the trial (Figure 1). The Weibull was chosen because it is a flexible class of distributions that allows for increasing or decreasing hazard over

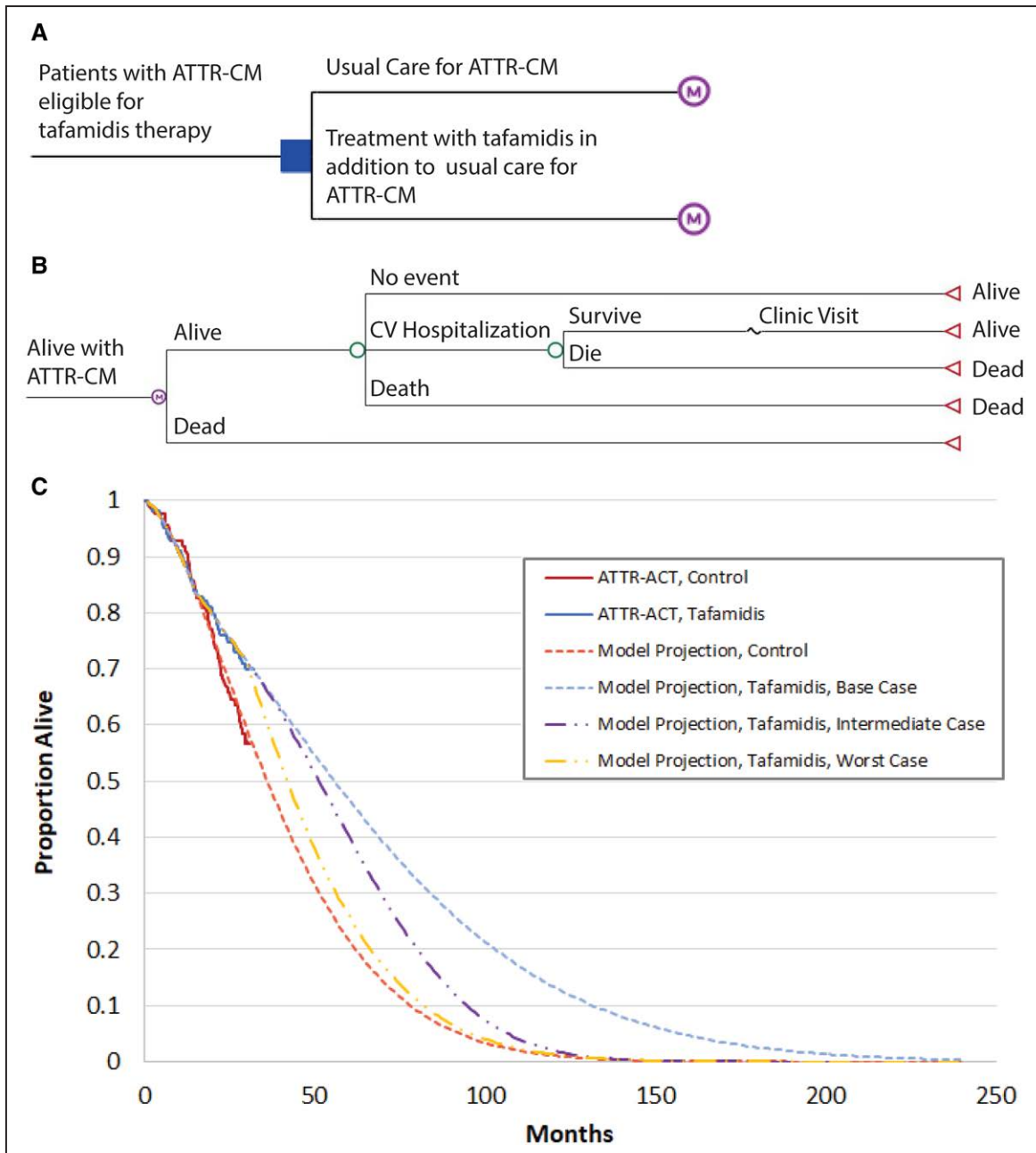


Figure 1. Schematic of model and model calibration.

We developed a state-transition Markov model to evaluate the cost-effectiveness of tafamidis therapy compared with usual care among patients with symptomatic heart failure from transthyretin amyloid cardiomyopathy (ATTR-CM; **A**). In monthly cycles, patients could experience cardiovascular hospitalizations (some proportion of which were fatal) or die from other causes (**B**). In the ATTR-ACT trial (Transthyretin Amyloidosis Cardiomyopathy Clinical Trial), treatment with tafamidis compared with usual care reduced the risk of cardiovascular hospitalizations throughout the course of therapy, and the risk of death after the first 18 months of treatment. Over the initial 30 months, the model reproduced survival rates seen in the tafamidis and control arms in the ATTR-ACT trial (**C**). The model used a parametric (Weibull) model to project long-term survival in the control arm beyond 30 months. The base case assumed that the effectiveness of tafamidis would be preserved beyond 30 months (best-case scenario). In sensitivity analyses, we modeled an intermediate-case scenario that assumed that the effectiveness of tafamidis gradually would wane beyond 30 months so that there would be no meaningful differences between the control and intervention groups beyond 90 months, and a worst-case scenario that assumed a complete loss of effectiveness of tafamidis beyond 30 months (**C**). See text for additional modeling details. CV indicates cardiovascular.

time (eg, increasing cardiovascular mortality with age) and covers simpler distributions such as the exponential distribution.¹⁸ We used parametric bootstrapping to estimate the uncertainty of the Weibull curve, assuming a bivariate normal joint distribution of the estimates of its σ and κ parameters (Table 1). As observed in ATTR-ACT, we assumed that survival

in the intervention arm was identical to that in the control arm for the first 18 months. We then used the Weibull models described earlier, on the basis of the published survival curves from the trial, to model the reduction in all-cause mortality in the intervention arm relative to the control arm between months 18 and 30.

We assumed that patients in the control arm would have an average of 0.70 cardiovascular hospitalizations per year (95% CI, 0.62–0.80) as observed in ATTR-ACT, and applied a 32% hazard reduction in the tafamidis arm (Table 1).²

Extrapolation Beyond Trial Duration

Because patients enrolled in ATTR-ACT were followed for only 30 months, we used the Weibull model described earlier to project survival in the control arm beyond 30 months. In the base case, we made the optimistic assumption that the benefits of tafamidis would be sustained beyond 30 months, so that the hazard ratio for survival observed in month 30 would continue throughout the duration of therapy. We also assumed that the monthly rate of decline in mean quality of life in each arm would continue unchanged beyond 30 months. These assumptions favored tafamidis and represented a best-case scenario for the cost-effectiveness of tafamidis compared with usual care (Table I in the Data Supplement). In sensitivity analyses, we modeled (1) an intermediate-case scenario that assumed that the effectiveness of tafamidis waned over the 60 months after trial completion so that there was no difference between the intervention and control arms beyond month 90; and (2) a worst-case scenario that assumed that tafamidis becomes completely ineffective after month 30.

Adverse Events

In ATTR-ACT, the safety profile of tafamidis appeared to be similar to placebo at 30 months. We therefore did not include any costs and quality-of-life penalties related to medication-related adverse events in the model.

Costs

We assumed that 1 year of tafamidis therapy would cost \$225 000, its wholesale acquisition cost in September 2019 (Tafamidis Dose and Pricing in the Data Supplement).⁷ We varied this assumption in sensitivity analyses. The cost of cardiovascular hospitalizations was estimated from the 2014 Healthcare Cost and Utilization Project data using Ninth Revision of International Classification of Diseases codes, adjusted to include physician fees (Table II in the Data Supplement).^{9,10} Because ATTR-CM has substantial prognostic implications for patients and, in the case of hereditary ATTR-CM, for family members, we assumed that patients with HFpEF would be tested for ATTR-CM regardless of the decision to initiate tafamidis therapy. We therefore did not incorporate diagnostic costs in this analysis because their inclusion would not be expected to alter the incremental cost-effectiveness of tafamidis therapy. Background healthcare costs (defined as all direct medical costs, excluding cardiovascular hospitalizations and tafamidis drug costs) were estimated as the adjusted, survey-weighted mean total expenditures for individuals with history of heart failure and without any cardiovascular hospitalizations in the previous year or during the survey year from the 2006–2015 Medical Expenditure Panel Survey, stratified by age.⁸ We included long-term care costs by multiplying the proportion of all US adults using each type of long-term care service by published annual long-term care cost estimates from the US Department of Health and Human Services (Tables III and IV in the Data Supplement).^{14,15} All costs were

inflated to 2019 US dollars using the Personal Consumption Expenditure index.¹⁶ Additional modeling details are available in the Data Supplement.

Quality-of-Life Estimates

ATTR-ACT used the overall score of the KCCQ (Kansas City Cardiomyopathy Questionnaire; KCCQ-OS) to measure study participants' heart failure-specific health status at baseline and throughout follow-up.¹⁷ We used observed changes in the KCCQ-OS from ATTR-ACT (placebo, 20.81±1.97 vs tafamidis, 7.16±1.42) in the first 30 months of the model and linearly extrapolated these afterward. To map KCCQ-OS scores to quality-of-life weights, we developed a mapping algorithm using individual-level data from a prospective, 14-center cohort of 476 outpatients with heart failure (Estimating Quality-of-Life Parameters, Tables V and VI in the Data Supplement).¹⁹ To capture the uncertainty in this mapping process, we used parametric bootstrapping to generate 1000 paired values for the mapping parameters, which we incorporated into probabilistic sensitivity analyses.²⁰ Because patients with HFpEF typically receive other oral medications such as diuretics, we did not model any additional pill-related disutility related to tafamidis therapy.

Main Outcome Measures

The primary outcome was the incremental cost-effectiveness ratio (ICER) of tafamidis compared with usual care, assessed in terms of both cost per life-year and cost per quality-adjusted life-year (QALY). We assumed a cost-effectiveness threshold of \$100 000 per QALY, and examined alternative thresholds in sensitivity analyses (high value, <\$50 000; intermediate value, ≥\$50 000 to <\$150 000; and low value, ≥\$150 000 per QALY gained).²¹ We also evaluated the effect on annual healthcare spending if all US patients eligible for tafamidis were to receive the drug. For this budget impact analysis, we estimated a target population of 120 000 US adults, on the basis of a conservative estimate that 4% of adults older than 60 years who have HFpEF have ATTR-CM, but varied this number between 100 000 to 200 000 in sensitivity analyses (Approach to the Budget Impact Analysis in the Data Supplement). We first estimated total change in healthcare spending over 5 years and then generated annualized estimates of budget impact.

Sensitivity Analyses

We performed deterministic and probabilistic sensitivity analyses to reflect uncertainty in the key parameters. In deterministic analyses, we varied input parameters one at a time across the range shown in Table 1 while holding all other parameters at their base-case value. Probabilistic sensitivity analyses were performed by drawing (with replacement) 10 000 sets of input parameters from prespecified statistical distributions to generate 95% uncertainty intervals (UI) for key clinical and economic outcomes as well as acceptability curves.

Software

Modeling was performed using TreeAge Pro 2019 (TreeAge Software Inc, Williamstown, Massachusetts) and Microsoft Excel version 16 (Microsoft Corporation, Redmond,

Washington), and statistical analyses were performed using R version 3.6.1 (Vienna, Austria).

RESULTS

Model Calibration

The mean age of the simulated cohort was 74.5 years, and 11% were women. The model accurately replicated the all-cause mortality and cardiovascular hospitalization rates observed in ATTR-ACT over 30 months of follow-up (Table VII in the Data Supplement). For example, all-cause mortality at 30 months among patients receiving tafamidis was 29.6% in the model and 29.5% in ATTR-ACT. At 30 months, the HR for all-cause mortality (tafamidis vs usual care) was 0.68 (95% UI, 0.51–0.86) in the model compared with 0.70 (95% CI, 0.51–0.96), and the relative risk ratio for cardiovascular hospitalizations was 0.70 (95% UI, 0.59–0.83) in the model versus 0.68 (95% CI, 0.56–0.81) in ATTR-ACT (Table VII in the Data Supplement).

Base-Case Analysis

Mean survival in the usual care arm was 3.46 (95% UI, 2.88–4.25) years; this was prolonged to 5.43 (95% UI, 4.17–6.76) years in the tafamidis arm (Table 2). Patients receiving tafamidis were projected to have fewer cardiovascular hospitalizations over the first 30 months compared with patients receiving usual care, but this was offset by additional hospitalizations over the long-term because of increased survival, resulting in a higher total number of lifetime cardiovascular hospitalizations in patients receiving tafamidis (Table 2 and Table VIII in the Data Supplement). Compared with usual care, treatment with tafamidis over the lifetime horizon was projected to generate 1.29 (95% UI, 0.60–1.89) additional QALYs at an incremental cost of \$1 135 000 (95% UI, 872 000–1 377 000), resulting in an ICER of \$880 000 (95% UI, 697 000–1 553 000) per QALY gained (Table 2). The incremental cost in the intervention arm almost entirely comprised the cost of tafamidis (\$1 086 000 [95% UI, 861 000–1 303 000]), with a small contribution from increased background costs related to prolonged survival (Table 2). There was no meaningful reduction in lifetime costs of cardiovascular care because savings from fewer cardiovascular hospitalizations per year were offset by increased cardiovascular costs in the added years of life.

Sensitivity Analyses

In deterministic analyses, our findings were sensitive to 3 key parameters. First, an increase in the discount rate to 8% increased the ICER to \$977 000 per QALY gained. Second, assuming a lower effectiveness of tafamidis with regard to reduction in all-cause mortality would

Table 2. Base Case Results

	Usual Care	Tafamidis
Healthcare outcomes		
Survival, life years*	3.46 (2.88–4.25)	5.43 (4.17–6.76)
Survival, life year†	3.23 (2.73–3.84)	4.83 (3.82–5.79)
Incremental life year†	Comparator	1.60 (0.48–2.47)
Quality-adjusted survival, quality-adjusted life-years†	2.19 (1.94–2.56)	3.48 (2.85–4.15)
Incremental quality-adjusted life-years†	Comparator	1.29 (0.47–1.75)
No. of cardiovascular hospitalizations	2.36 (1.87–3.02)	2.53 (1.78–3.43)
Direct healthcare costs		
Lifetime healthcare costs, 2019 US dollar†	126 000 (105 000–157 000)	1 262 000 (996 000–1 515 000)
Spending on tafamidis	—	1 086 000 (861 000–1 303 000)
Spending on cardiovascular hospitalizations	34 000 (26 000–46 000)	34 000 (23 000–47 000)
Background healthcare costs	92 000 (77 000–113 000)	142 000 (110 000–174 000)
Incremental healthcare costs, 2019 US dollar†	Comparator	\$1 135 000 (872 000–1 377 000)
Incremental cost-effectiveness ratio		
US dollars per life-year gained	Comparator	\$709 000 (547 000–1 943 000)
US dollars per quality-adjusted life-year gained	Comparator	\$880 000 (697 000–1 564 000)

*Undiscounted.

†Discounted.

increase the ICER to \$1 321 000 per QALY gained. Third, the ICER was sensitive to the annual cost of tafamidis. A 92.6% price reduction from \$225 000 to \$16 563 would make tafamidis cost-effective at a threshold of \$100 000 per QALY gained, whereas an 87% price reduction to \$29 925 would make it cost-effective at \$150 000 per QALY gained (Figure 2). In addition, shortening the time horizon to 30 months, the duration of ATTR-ACT, increased the ICER to \$3 903 000 per QALY gained (Table VIII in the Data Supplement). The model was not sensitive to other parameters (altering the ICER by less than 20%).

In probabilistic sensitivity analyses, tafamidis was cost-effective in 0% of the 10 000 probabilistic simulations at a cost-effectiveness threshold of \$100 000 per QALY gained (Figure 3 and Figure I in the Data Supplement).

Scenario Analyses

The results were sensitive to the long-term durability of effectiveness of tafamidis. Assuming that the effectiveness of tafamidis wanes over 5 years after trial completion (intermediate-case scenario) reduced the incremental benefit of tafamidis to 0.63 QALYs and increased

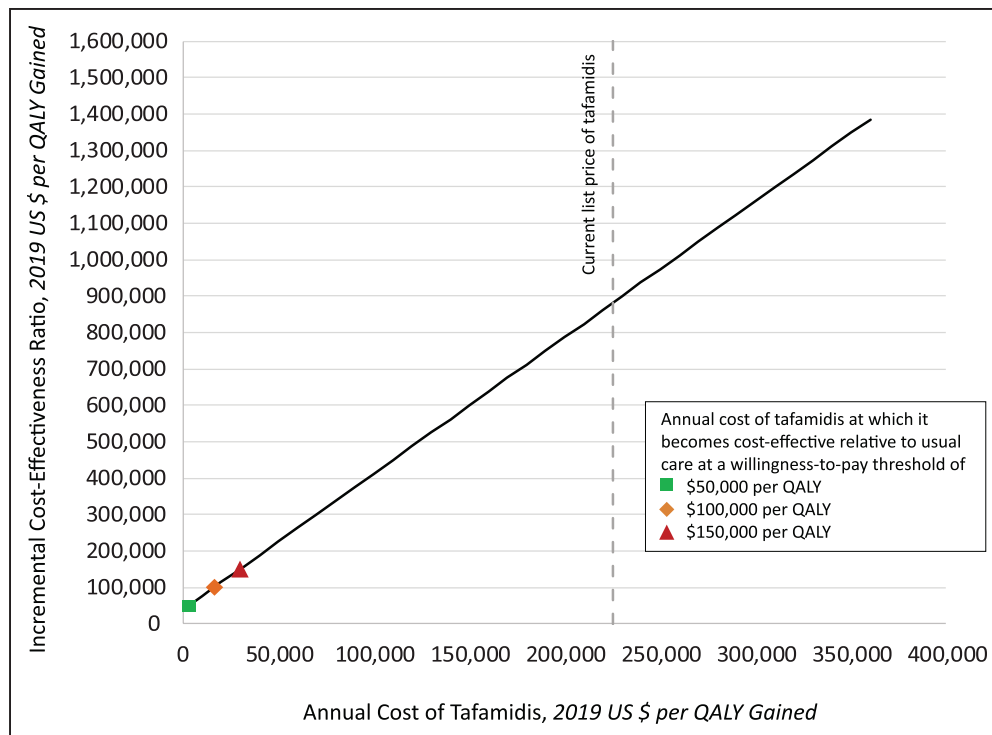


Figure 2. One-way sensitivity analysis by price of tafamidis.

We evaluated the effect of varying the annual cost of tafamidis on the incremental cost-effectiveness ratio of tafamidis compared with usual care, holding all other input parameters at their base-case value. At the 2019 annual price of \$225 000, tafamidis does not meet conventional cost-effectiveness thresholds. An 86.7% reduction in price to \$29 925 would be needed to achieve a threshold of \$150 000 per quality-adjusted life-year (QALY) gained, a 92.6% reduction in price to \$16 563 would be needed to meet a cost-effectiveness threshold of \$100 000 per QALY gained, and a 98.6% reduction to \$3 200 would be needed to achieve a cost-effectiveness threshold of \$50 000 per QALY gained.

the ICER to \$1 517 000 per QALY gained (Table IX in the Data Supplement). Assuming complete loss of tafamidis effectiveness beyond 30 months (worst-case scenario) increased the ICER to \$3 122 000 per QALY gained. In the intermediate- and worst-case scenarios, the price of tafamidis would need to be 95.7% and 97.4% lower, respectively, for the therapy to be cost-effective at a threshold of \$100 000 per QALY gained (Table X in the Data Supplement).

Budget Impact Analysis

Treating all eligible US patients with ATTR-CM with tafamidis (n=120 000) was projected to increase annual healthcare spending by \$32.3 billion. Nearly all of the budget impact (\$31.9 billion) was because of the cost of tafamidis. The change in healthcare spending varied with estimated prevalence of ATTR-CM, ranging from \$26.9 billion if the prevalence was assumed to be 100 000 to \$53.8 billion if the prevalence was assumed to be 200 000.

DISCUSSION

In a simulation model calibrated to the results of the ATTR-ACT trial, we found that tafamidis therapy for patients with ATTR-CM would increase quality-adjusted

life expectancy by an average of 1.29 QALYs, but the ICER of \$880 000 per QALY gained would be substantially higher than conventional cost-effectiveness thresholds. A 92.6% reduction in the annual price of tafamidis, from \$225 000 to \$16 563, would be needed for the drug to be cost-effective at a commonly accepted threshold of \$100 000 per QALY gained. Savings from fewer cardiovascular hospitalizations per patient per year would be offset by increases in healthcare costs related to prolonged survival. As such, US healthcare spending would increase by \$32.3 billion a year if all eligible patients were to receive tafamidis therapy. This includes a \$31.9 billion increase in annual prescription drug expenditures, which would increase the total US spending for all prescription drugs by 9.3% (from \$344 billion in 2018 to \$375.9 billion).²² As diagnosis rates increase, as a result of greater awareness about ATTR-CM, increased use of nuclear scintigraphy for accurate diagnosis, and more widespread uptake of genetic tests to screen family members of individuals with variant ATTR-CM, the budget impact of tafamidis is expected to increase as well.²³ The challenge for health systems and payers is therefore likely to grow over time. Our findings are concordant with those of 2 previous analyses that found that tafamidis was not cost-effective for ATTR familial amyloid polyneuropathy in Europe.^{24,25} However, our analysis is the first to examine tafamidis

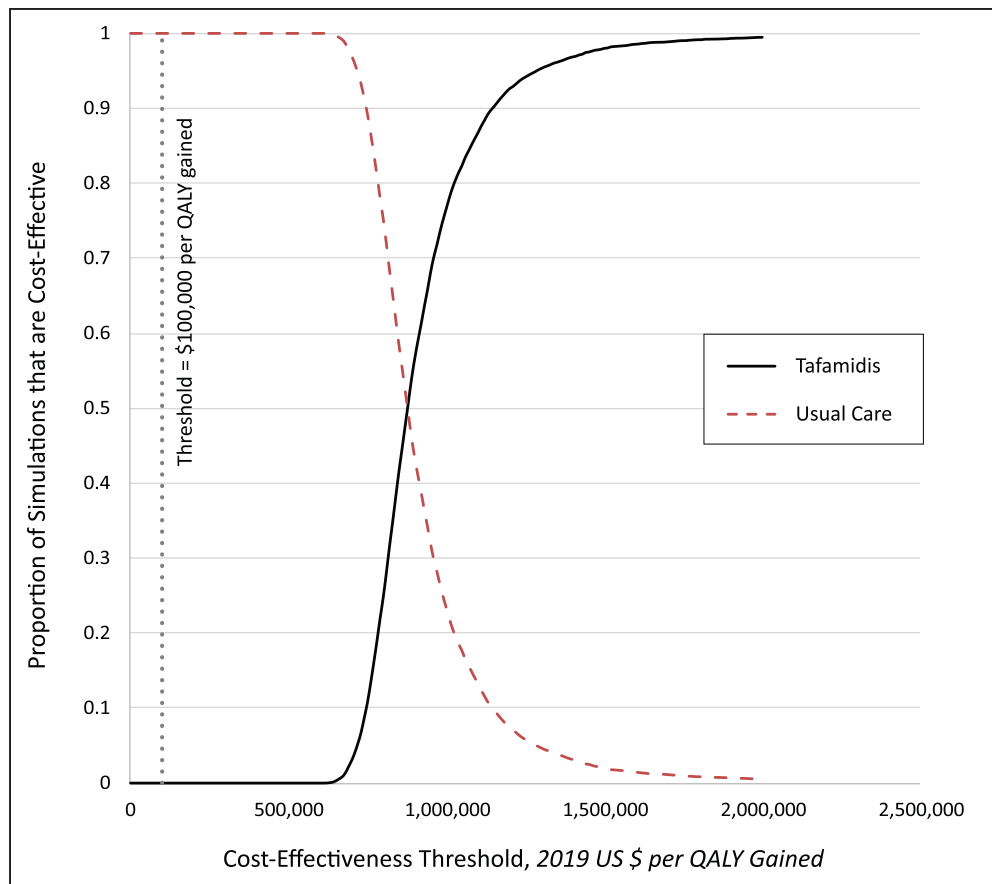


Figure 3. Cost-effectiveness acceptability curves.

In probabilistic sensitivity analyses, we ran 10 000 iterations of the model after sampling key input parameters from prespecified statistical distributions (with replacement). The results are shown below as acceptability curves, which indicate the proportion of simulations (y axis) in which a given strategy is the optimal strategy at various cost-effectiveness thresholds (x axis). Under our base case assumptions and assuming a societal cost-effectiveness threshold of \$100 000 per quality-adjusted life-year (QALY), treatment with tafamidis was cost-effective compared with usual care in 0% of the simulations.

from a US healthcare sector perspective and include the survival benefits observed in ATTR-ACT.

Over the past 3 decades, numerous cost-effective and potentially life-saving therapies have been approved and implemented for heart failure with reduced ejection fraction, but pharmaceutical innovation for HFpEF has largely been disappointing. One potential explanation for the difficulty in developing effective therapies for HFpEF is that it represents a heterogeneous group of conditions that are unlikely to all respond to a single therapy, arguing against a one-size-fits-all approach. Given this heterogeneity, HFpEF is an ideal syndrome for the application of precision medicine, and recent efforts have focused on identifying subgroups of HFpEF to tailor therapy accordingly. The recognition of ATTR-CM as a distinct phenotype of HFpEF, the use of nuclear scintigraphy to noninvasively and accurately diagnose ATTR-CM, and the development of tafamidis to inhibit a key step in the pathogenesis of ATTR-CM are therefore major advances in the targeted treatment of the HFpEF syndrome.² Our study suggests that for patients similar to those in the ATTR-ACT trial, tafamidis therapy for ATTR-CM will prolong quality-adjusted survival by

1.29 QALYs, a relatively large health gain compared with other contemporary cardiovascular therapies, justifying its designation as a breakthrough therapy that addresses an important unmet clinical need.^{26,27} For comparison, the use of sacubitril-valsartan in heart failure with reduced ejection fraction is projected to yield 0.62 QALYs over a patient's lifetime.²⁶

However, these substantial health benefits of tafamidis are projected to have a high cost. Our study demonstrates that, at current drug prices, widespread uptake of tafamidis would produce a large increase in healthcare spending, with an ICER that greatly exceeds US thresholds for high or even intermediate economic value. Although manufacturers typically offer discounts and rebates amounting to 25% to 30% of the wholesale acquisition cost, our findings suggest that massive discounts or price reductions would be needed in order to make tafamidis economically attractive at conventional thresholds. It should be noted, however, that manufacturers of rare drugs have substantial pricing power, so that these drugs are often discounted less than 5% if at all. Moreover, manufacturers' discounts do little to alleviate the financial burden for

Medicare Part D beneficiaries—who, given the natural history of the disease, are likely to represent the majority of US patients eligible for this novel therapy—because their copayments are calculated from the list price of the drug before the application of any rebates or discounts. As a result, Medicare Part D beneficiaries without secondary insurance may be responsible for tens of thousands of dollars per year in out-of-pocket costs. This would put the drug out of reach for many fixed-income seniors.

In many ways, tafamidis is emblematic of contemporary challenges in rewarding pharmaceutical innovation; it is a highly personalized therapy that is effective, safe, and unaffordable. Its expedited FDA approval in May 2019 relied on several regulatory and financial incentives available to manufacturers of orphan drugs that target rare diseases without preexisting treatments.^{28,29} These incentives, embedded in the Orphan Drug Act and designed to help patients gain expedited access to transformative therapies, have been spectacularly successful in spurring pharmaceutical innovation: 58% of all new drugs approved in 2018 were for a rare-disease indication.³⁰ But once approved, drugs that receive orphan drug status typically enter the market at a very high price: the 100 best-selling rare disease drugs in 2017 cost an average of \$116 000 more than 100 best-selling drugs for other indications.³¹ Innovators have argued that these higher prices are necessary to recoup large investments in research and development when only a small number of patients are eligible for therapy. However, the high price tag defeats the purpose of the expedited approval process because it makes the drug unaffordable for the target population. The case of tafamidis lends further credence to recent calls to reform the Orphan Drug Act to ensure access to the rare-disease drugs that use its incentives. For example, regulatory and financial incentives could be conditioned on the manufacturer setting a value-based price, on the basis of an appropriate cost-effectiveness threshold for rare-disease drugs.³⁰ In return, payers would cover these drugs without onerous preauthorization requirements or large copayments, eliminating financial barriers to access and adherence. Although the details would need to be worked out, it is clear that a framework for the responsible pricing of novel therapies guided by rigorous and timely value-based assessments is urgently needed to ensure broad access.

Recent experience with other high-price cardiovascular medications such as proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors may foretell the adoption patterns for tafamidis. Launched in 2016 at an average price of \$14 350 per year and with a potential target population of 10 million US adults, PCSK9 inhibitors saw their uptake stymied because of a combination of onerous preauthorization requirements (related to high drug costs for payers) and frequent prescription

abandonment (related to high out-of-pocket costs for patients).^{32,33} Subsequently, a series of independent cost-effectiveness analyses argued for a 70% to 80% price reduction to meet conventional cost-effectiveness thresholds. Other studies showed that average annual out-of-pocket costs for a Medicare Part D beneficiary receiving a PCSK9 inhibitor and a generic statin was \$5000.^{33,34} In 2019, both manufacturers announced an unprecedented 60% price reduction in an effort to increase uptake. We suspect that the widespread adoption of tafamidis is likely to face similar hurdles. Unless the price of the drug falls substantially, onerous preauthorization requirements and high out-of-pocket costs are likely to present substantial hurdles to widespread adoption. Consequently, the projected population health gains with tafamidis are unlikely to be achieved at 2019 prices.

Limitations

Our study has a few limitations. Our estimates of the efficacy and safety of tafamidis were based on a single randomized clinical trial with a mean follow-up of 30 months and should be updated when longer follow-up data and information regarding high-risk subgroups become available. We have previously argued that the life-cycle approach advocated by the National Academy of Medicine to evaluate the safety and effectiveness of drugs on the basis of new data should be extended to cost-effectiveness evaluations.³⁴ Our base-case analysis assumed an annual drug price equivalent to the wholesale acquisition cost of tafamidis before any discounts or rebates offered by the manufacturer. However, our findings suggest that the typical discounts are not likely to make the drug cost-effective. We did not incorporate the cost of provider time spent on meeting onerous preauthorization requirements often introduced by payers to limit uptake of expensive medications, the clinician time spent appealing initial denials, or the effect of delays in initiating treatment. We did not model the costs or consequences of cardiac transplantation and cardiac-assist devices, which are uncommon in patients with ATTR-CM because the average age at diagnosis in the United States is 70 to 75 years. If future diagnostic advances facilitate the diagnosis of amyloid cardiomyopathy at younger ages, and should tafamidis therapy in younger patients alter the rates of transplantation or implantation of cardiac-assist devices during follow-up, this cost-effectiveness analysis would need to be updated to include the high cost of these procedures. Health-related quality-of-life data were not directly available for trial participants in ATTR-ACT; we therefore estimated quality-of-life data from published KCCQ-OS estimates. Our budget impact evaluation was based on current estimates of the prevalence of ATTR-CM, which several experts believe to be an underestimate of its

true prevalence. If rates of diagnosis of ATTR-CM substantially increase because of more widespread application of nuclear scintigraphy and genetic testing, as well as from greater awareness of the condition, the effect of tafamidis therapy on total health spending would exceed our projections.

CONCLUSIONS

In a disease-simulation model calibrated to the results of the ATTR-ACT trial, treatment with tafamidis is projected to produce substantial clinical benefit but would greatly exceed conventional cost-effectiveness thresholds at the current list price. On the basis of recent US experience with high-cost cardiovascular medications, access to and uptake of this effective therapy may be limited unless there is a large reduction in drug costs.

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VIEWPOINT

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Tafamidis—A Pricey Therapy for a Not-So-Rare Condition

On May 3, 2019, the US Food and Drug Administration (FDA) announced approval of the first treatments for cardiomyopathy caused by transthyretin amyloidosis (ATTR-CM). The FDA called the approvals of tafamidis meglumine and tafamidis “an important advancement” in the treatment of ATTR-CM, a “rare, debilitating, and often fatal disease.”¹ Both of the approved formulations are lifelong treatments. The FDA granted tafamidis meglumine fast track, priority review, and breakthrough therapy designations and tafamidis meglumine and tafamidis received orphan drug designations. The approval of these novel therapies, their potential applicability to a patient population larger than recognized by the FDA, and their very high price present important challenges associated with access and affordability that will affect patients, clinicians, payers, and policymakers. This Viewpoint discusses these issues and presents recommendations that have heightened relevance as novel, very expensive therapies continue to emerge for previously untreatable conditions.

Transthyretin amyloidosis is a late-onset disease primarily affecting older adults. The condition can be inherited as an autosomal dominant trait caused by pathogenic mutations in the transthyretin gene *TTR* (ATTRv) or by the deposition of wild-type transthyretin protein (ATTRwt). The FDA granted its approval primarily based on clinical trial findings of the Transthyretin Amyloidosis Cardiomyopathy Clinical Trial (ATTR-ACT).² ATTR-ACT showed that treating patients with ATTR-CM (ATTRm or ATTRwt) with tafamidis meglumine vs placebo for 30 months reduced all-cause mortality, with a number needed to treat of 7.5 to prevent 1 death. Treatment also reduced the rate of cardiovascular-associated hospitalizations, with a number needed to treat of 4 to prevent 1 hospitalization in a year. Furthermore, treatment slowed declines in functional capacity and quality of life.

Both agents carry a high price tag with a wholesale acquisition cost (the “list” price) of \$225 000 per year. While this is lower than the price of other ATTR drugs (inotersen and patisiran) approved for treating polyneuropathy in hereditary transthyretin-mediated amyloidosis (but not ATTR-CM), tafamidis meglumine and tafamidis are still the world’s most expensive medications for cardiovascular disease. Annual sales are projected to exceed \$1 billion by 2024, but this estimate could prove conservative as the prevalence of ATTR-CM increases because of greater awareness and higher rates of diagnosis.

The FDA orphan drug designation applies to drugs designed to treat a disease or condition affecting fewer than 200 000 persons in the United States. According to the manufacturer’s press release, “it is estimated that the prevalence of ATTR-CM is approximately 100 000 people in the US, and only one to two percent of those

patients are diagnosed today.”³ However, this may be a substantial underestimate of the number of patients eligible for these newly approved treatments. The findings of one study suggest that transthyretin amyloid cardiomyopathy (ATTRwt) may have a prevalence of 13% among patients hospitalized with heart failure with preserved ejection fraction and an increased wall thickness.⁴ As heart failure with preserved ejection fraction is the most common type of heart failure in older adults, the actual number of patients eligible for treatment with these agents could reach into the hundreds of thousands. In addition, the hereditary form of ATTR-CM (ATTRv) disproportionately affects African American individuals, in whom the *Val122Ile* mutation of the transthyretin gene is common (1 in 25). Although the phenotypic penetrance is reported to be low based on echocardiographic criteria, the high prevalence of this mutation and efforts to screen for it could ultimately increase the numbers of patients eligible for treatment. In addition, identifying patients with ATTR-CM has become more simplified. While tissue biopsy was previously required for diagnosis, a noninvasive approach using technetium-labeled bone scintigraphy coupled with an assessment for monoclonal proteins has been shown to be highly sensitive and specific for diagnosing ATTR-CM.⁵

The very high cost for these therapies raises questions about access and affordability. The most critical factor affecting access for patients is out-of-pocket costs, determined by deductibles, copayments, and coinsurance that are driven by the list price of a drug. The price of these agents will especially affect those with Medicare Part D in the coverage gap (“donut hole”) or in the catastrophic coverage phase during which the patient is responsible for up to 5% of drug costs, as well as those without health insurance or with high-deductible health plans.

From the perspective of the US health care sector, the primary issue is the number of people eligible for treatment. How much will the population eligible for treatment with these agents expand beyond the few thousand with a diagnosis today? Could the numbers of patients with diagnoses grow by 10- or 20-fold or even more, especially with greater ease of diagnosis, and with targeted screening of special, high-risk populations? The resulting budgetary impact on the health care sector could be staggering.

Assessing the effectiveness of alternative treatments for ATTR-CM could also be challenged by the high cost of tafamidis. In comparative efficacy trials, tafamidis should serve as the standard for comparison. Yet, the cost implications of implementing such a trial are daunting. For example, if a trial similar to ATTR-ACT was conducted with a tafamidis control arm, the costs for the drug alone could reach nearly \$100 million.

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The very high cost of these novel therapies raises serious concerns about assuring sustainable access to novel therapies for patients with previously untreatable conditions like ATTR-CM. Several policy recommendations follow from the lessons of tafamidis:

1. While pharmaceutical manufacturers should be rewarded for innovation, they should commit to responsible pricing of novel therapies guided by rigorous and transparent assessments of cost-effectiveness.^{6,7}
2. As competitors may lower prices, the FDA should accelerate the review of competitors of approved products that exceed the responsible price or acceptable budget impact thresholds.
3. If new data emerge indicating that the prevalence of a disease or condition actually exceeds 200 000, the awarding of an orphan drug designation by the FDA and its associated market exclusivity provisions should be revisited.
4. The very high price that manufacturers charge for breakthrough therapies can effectively forestall the initiation of trials with active comparators. High prices for a standard therapy should not be used to justify comparisons with placebos. The Centers for Medicare and Medicaid Services should explore options to

cover the costs of highly priced comparator therapies considered standard of care.

5. Cost-effectiveness/value assessments should be included in clinical practice guidelines. Frameworks to integrate the level of value into clinical guideline recommendations already exist and should be used in practice guidelines relevant to tafamidis.⁷

The approval of tafamidis meglumine and tafamidis by the FDA represents the culmination of decades of basic research combined with the efforts of the US pharmaceutical industry, leading to the development of a breakthrough treatment for a previously untreatable disease. While the recovery of the substantial research and development costs associated with these therapies is appropriate, the very high prices for tafamidis meglumine and tafamidis are not justified and appear to be a particularly egregious example of price gouging. It would be unfortunate if the very high prices charged for these agents hindered access for those most likely to benefit and slowed clinical advances in the management of this not-so-rare condition. As additional novel therapies for previously untreatable diseases are developed, tested, and marketed, we have much to learn from the ensuing experience with tafamidis.

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FOR IMMEDIATE RELEASE

Thursday, May 24, 2018

Pfizer Agrees to Pay \$23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical company Pfizer Inc. has agreed to pay \$23.85 million to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively "co-pays"). These co-pay obligations may be substantial for expensive medications. Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

As part of today's settlement, the government alleged that Pfizer used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the co-pay obligations of Medicare patients taking three Pfizer drugs, Sutent and Inlyta, which both treat renal cell carcinoma, and Tikosyn, which treats arrhythmia in patients with atrial fibrillation or atrial flutter. The government alleged that, in order to generate revenue and instead of giving Sutent and Inlyta to Medicare patients who met the financial qualifications of Pfizer's existing free drug program, Pfizer worked with a third-party specialty pharmacy to transition some portion of those patients to the foundation, which covered the patients' Medicare copays and caused Medicare claims to result from the filling of the patients' Sutent and Inlyta prescriptions. In connection with this initiative, according to the government's allegations, Pfizer made donations to the foundation and thereafter received data from the foundation, via the specialty pharmacy, confirming that the foundation funded the Medicare copays of Sutent and Inlyta patients. With respect to Tikosyn, Pfizer raised the wholesale acquisition cost of a package of forty .125 mg capsules of the drug by 44 percent during the last three months of 2015. Knowing the price increase would increase Medicare beneficiaries' copay obligations for Tikosyn, which could result in more Medicare patients needing financial assistance to fill their Tikosyn prescriptions, Pfizer allegedly worked with the foundation to create and finance a fund for Medicare patients being treated for arrhythmia with atrial fibrillation or atrial flutter. According to the allegations in the settlement agreement, Pfizer coordinated the timing of the opening of the fund for these patients with the implementation of a Tikosyn price increase, and Pfizer then began referring to the foundation any Medicare patients who needed

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financial assistance to meet their newly-increased copays for the drug. For the next nine months, Tikosyn patients accounted for virtually all of the beneficiaries of the fund.

“Pfizer used a third party to saddle Medicare with extra costs,” said United States Attorney Andrew E. Lelling. “According to the allegations in today’s settlement agreement, Pfizer knew that the third-party foundation was using Pfizer’s money to cover the co-pays of patients taking Pfizer drugs, thus generating more revenue for Pfizer and masking the effect of Pfizer’s price increases. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these. At the same time, we commend Pfizer for stepping forward to resolve these issues in a responsible manner.”

“Kickbacks undermine the independence of physician and patient decision-making, and raise healthcare costs,” said Acting Assistant Attorney General Chad A. Readler of the Justice Department’s Civil Division. “As today’s settlement makes clear, the Department will hold accountable drug companies that pay illegal kickbacks—whether directly or indirectly—to undermine taxpayer funded healthcare programs, including Medicare.”

“Today’s settlement demonstrates the FBI’s commitment to making sure patients receive, and the government pays for, health care that is not compromised by kickbacks,” said Harold H. Shaw, Special Agent in Charge, FBI Boston Division. “What Pfizer is accused of doing in this case—masking charitable contributions to increase company profits-- violates the basic trust patients extend to the healthcare system and threatens the financial integrity of the Medicare program.”

Pfizer also has entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that Pfizer implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from company executives and Board members, and the implementation of a risk assessment and mitigation process.

“Our corporate integrity agreement promotes independence between Pfizer and any patient assistance programs to which it may donate,” said Gregory E. Demske, Chief Counsel to the Inspector General for the United States Department of Health and human Services. “Without true independence, as we have seen in this case, drug companies may use patient assistance programs as conduits for improper payments that harm Medicare.”

U.S. Attorney Lelling, Acting Assistant Attorney General Readler, HHS-OIG Chief Counsel Demske, and FBI SAC Shaw made the announcement today. This matter was investigated by HHS-OIG, the Federal Bureau of Investigation, the United States Postal Inspection Service, and the United States Department of Veterans Affairs Office of Inspector General. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro, Abraham George, and Deana El-Mallawany of Lelling’s Office, and by Trial Attorneys Augustine Ripa and Sarah Arni of the Justice Department’s Civil Division.

Attachment(s):

[Download Pfizer Settlement Agreement.pdf](#)

Topic(s):

Health Care Fraud

Component(s):

[USAO - Massachusetts](#)

Updated May 24, 2018

PFE000481

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PFIZER INC.**

I. PREAMBLE

Pfizer Inc. (Pfizer) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Pfizer is entering into a Settlement Agreement with the United States.

Prior to the Effective Date, Pfizer established a compliance program that Pfizer represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program requirements (Compliance Program). Pfizer shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Pfizer may modify the Compliance Program as appropriate. However, at a minimum, Pfizer shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Pfizer under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Pfizer's final Annual Report; or (2) any additional materials submitted by Pfizer pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

- a. all owners of Pfizer who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading);
- b. all officers and directors of Pfizer;
- c. all U.S. employees of Pfizer who engage in or supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.5); and
- d. all U.S. contractors, subcontractors, agents, and other persons (including contract sales personnel) who perform any of the Covered Functions on behalf of Pfizer and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), consumers or independent third-party patient assistance programs; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Pfizer employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to perform a Covered Function for Pfizer more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for Pfizer during the calendar year.

2. “Government Reimbursed Products” refers to all Pfizer products that are: (a) marketed or sold by Pfizer in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Pfizer’s review and approval processes for promotional materials and any applicable review committee(s).

4. The term “Patient Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or cash or in kind donations provided by Pfizer or any entity acting on behalf of Pfizer to any independent third-party patient assistance program (Independent Charity PAP) (collectively, “Independent Charity PAP Related Functions”); and (b) the operation of, or participation in, any patient assistance program by Pfizer or any entity acting on behalf of Pfizer that provides free drugs to patients, including Federal health care program beneficiaries (i.e., Pfizer’s internal free drug program) or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards) (programs described under Section II.C.4.b shall be collectively referred to as “Pfizer PAPs”).

5. The term “Covered Functions” refers to “Promotional Functions” and “Patient Assistance Related Functions,” collectively.

6. The term "Third Party Personnel" refers to personnel who engage in Promotional Functions who are employees of entities with which Pfizer has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. Pfizer represents that: (1) Third Party Personnel are employed by entities other than and independent of Pfizer; (2) Pfizer does not control Third Party Personnel; and (3) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Pfizer agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.C.4, V.A.7, and V.B.6. Provided that Pfizer complies with the requirements of Sections III.C.4, V.A.7, and V.B.6, Pfizer shall not be required to fulfill the other CIA obligations that

would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Pfizer shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations.

1. *Compliance Officer.* To the extent not already accomplished, within 90 days after the Effective Date, Pfizer shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Pfizer; shall report directly to the Chief Executive Officer of Pfizer; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Pfizer. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Regulatory and Compliance Committee of the Board of Directors of Pfizer and shall be authorized to report on such matters to the Regulatory and Compliance Committee at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Pfizer as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

*Corporate Integrity Agreement
Pfizer Inc.*

Pfizer shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* To the extent not already accomplished, within 90 days after the Effective Date, Pfizer shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, human resources, audit, finance, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Pfizer's risk areas and shall oversee compliance monitoring and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Pfizer shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Regulatory and Compliance Committee of the Pfizer Board of Directors (RCC) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The RCC must include independent (i.e., non-executive) members.

The RCC shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Pfizer's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken,

such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the RCC, summarizing its review and oversight of Pfizer's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Regulatory and Compliance Committee of the Pfizer Board of Directors (RCC) has made a reasonable inquiry into the operations of Pfizer's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the RCC has concluded that, to the best of its knowledge, Pfizer has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the RCC is unable to provide such a conclusion in the resolution, the RCC shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Pfizer.

Pfizer shall report to OIG, in writing, any changes in the composition of the RCC, or any actions or changes that would affect the RCC's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Pfizer employees (Certifying Employees) are specifically expected to supervise and oversee activities within their areas of authority and shall annually certify that the applicable Pfizer business unit is compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Vice President, Corporate Responsibility; Regional President North America,

Vaccines; Regional President North America, Oncology; Regional President North America, Inflammation & Immunology; Regional President North America, Rare Disease; Regional President North America, Internal Medicine; US President, Retail; US President, Institutions; and Vice President, US Payer Channel & Access Lead. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Pfizer policies, and I have taken steps to promote such compliance. To the best of my knowledge, the _____ [insert name of department or functional area] of Pfizer is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Pfizer shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards.

Within 120 days after the Effective Date, Pfizer shall implement written policies and procedures regarding the operation of its compliance program in the United States, including the compliance program requirements outlined in this CIA and Pfizer's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Pfizer shall enforce its Policies and Procedures and shall make such compliance an element in evaluating the performance of all employees.

The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Patient Assistance Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- b. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Pfizer's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Pfizer's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);
- c. the operation of, or participation in, any Pfizer PAP. These Policies and Procedures shall be designed to ensure that Pfizer's operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Pfizer's operation of or participation in any such Pfizer PAP complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

- d. the materials and information that may be distributed by appropriate Pfizer personnel about Independent Charity PAPs or Patient Assistance Related Functions and the manner in, and circumstances under, which appropriate Pfizer personnel may respond to request for information about Independent Charity PAPs or Patient Assistance Related Functions; and
- e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute and the False Claims Act; and (ii) applicable Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), Pfizer shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, Pfizer shall develop a written plan (Training Plan) that outlines the steps Pfizer will take to ensure that: (a) all Covered Persons receive at least annual training regarding Pfizer's CIA requirements and Compliance Program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Pfizer Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Pfizer shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *RCC Training.* Within 90 days after the Effective Date, Pfizer shall provide at least two hours of training to each member of the RCC. This training shall

address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the compliance program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the RCC and should include a discussion of OIG's guidance on board member responsibilities.

New members of the RCC shall receive the RCC Training described above within 30 days after becoming an RCC member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Pfizer shall make available to OIG, upon request, training materials and records verifying that Covered Persons and RCC members have timely received the training required under this section.

4. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Pfizer shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Pfizer's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of the Pfizer Compliance Program. Pfizer shall attach or otherwise make available a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make Pfizer's Code of Conduct and a description of the Pfizer Compliance Program available to its Third Party Personnel; or (b) represent to Pfizer that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

D. Risk Assessment and Internal Review Process.

Within 120 days after the Effective Date, Pfizer shall develop and implement a centralized annual Risk Assessment and Internal Review Process to identify and address risks associated with each of Pfizer's Government Reimbursed Products and with applicable Federal health care program requirements. The Risk Assessment and Internal Review Process shall require compliance, legal, and department leaders at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with Pfizer's operation of any Patient Assistance Related Function and

the company's arrangements and interactions with any Independent Charity PAPs, (2) develop mitigation plans in response to the results of risk assessments performed, and (3) track the implementation of the mitigation plans in order to assess the implementation, status, or effectiveness of such plans. Pfizer shall maintain the Risk Assessment and Internal Review Process for the term of the CIA.

E. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Pfizer shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Pfizer shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Pfizer) related to the reviews.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions. The Systems Reviews shall assess Pfizer's systems, processes, policies, and procedures relating to the Covered Functions. Except as otherwise set forth in Appendix B, if there are no material changes in Pfizer's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Pfizer materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Reviews shall be performed for the second through fifth Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Pfizer identified by OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, OIG will consult with Pfizer and may consider internal audit and monitoring work conducted by Pfizer, the Government Reimbursed Product portfolio, the nature and scope of Pfizer’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Pfizer may propose to OIG that its internal audit(s) or monitoring be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. OIG retains sole discretion over whether, and in what manner, to allow Pfizer’s internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

OIG shall notify Pfizer of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Pfizer shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendix A and Appendix B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Pfizer a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO’s certification shall include a summary of current and prior engagements between Pfizer and IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Pfizer shall establish a Disclosure Program in the United States that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Pfizer's policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Pfizer shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Pfizer's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Division or appropriate individual(s) designated by Pfizer. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Pfizer shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

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- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in the Federal health care programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Pfizer shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Pfizer shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Pfizer shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.
- c. Pfizer shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Pfizer’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Pfizer understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Pfizer may be liable for overpayments and/or criminal, civil, and

administrative sanctions for employing or contracting with an excluded person regardless of whether Pfizer meets the requirements of Section III.G.

3. *Removal Requirement.* If Pfizer has actual notice that a Covered Person has become an Ineligible Person, Pfizer shall remove such Covered Person from responsibility for, or involvement with, Pfizer's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Pfizer has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Pfizer shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, Pfizer shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Pfizer conducted or brought by a U.S. governmental entity or its agents involving an allegation that Pfizer has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Pfizer shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable

to any Federal health care program for which penalties or exclusion may be authorized;

- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- c. the filing of a bankruptcy petition by Pfizer.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Pfizer determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Pfizer shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Pfizer shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.H above.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event; and
- d. a description of Pfizer's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.1.b, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Pfizer completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Independent Charity Patient Assistance Program Activities

To the extent that Pfizer makes monetary donations to Independent Charity PAPs, Pfizer shall implement the policies and practices set forth in this Section III.J within 120 days after the Effective Date.

1. *Role and Responsibilities of Independent Charity Group.* Pfizer shall vest sole responsibility and authority for developing the annual budget for Pfizer's donations to Independent Charity PAPs and for all other activities relating to Pfizer's donations to Independent Charity PAPs (including interactions with such PAPs) in a department or group within Pfizer known as the "Independent Charity Group. The Independent Charity Group shall be separate and independent from the commercial business units of Pfizer (referred to hereafter as the "commercial business units"). For purposes of this CIA, the commercial business units are the business units responsible for engaging in the sales and

marketing of Pfizer's Government Reimbursed Products. The Independent Charity Group shall operate independently from Pfizer's commercial business units. Pfizer's commercial business units shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Pfizer's donations to Independent Charity PAPs. Nothing in this provision limits the ability of Pfizer Executive Leadership Team (ELT) members to review, approve, and adjust the total amount available for donations in accordance with Pfizer's policies and procedures.

2. *Communications Regarding Pfizer's Donations to Independent Charity PAPs.* Pfizer shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Pfizer's donations to such PAPs. The commercial business units shall not communicate with, influence, or be involved in any communications with, or receive information from Independent Charity PAPs.

3. *Budgeting Process.* Pfizer shall establish a budget process to be followed for Pfizer's donations to Independent Charity PAPs. The Independent Charity Group shall develop the annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the legal and compliance departments. The commercial business units shall have no involvement in the budget or allocation process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Group from the commercial business units. The ELT (or a subset thereof) shall approve the total annual amount available for donations to Independent Charity PAPs. After the total annual amount is approved, the Independent Charity Group shall have sole responsibility for allocating the approved amount across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.

The Independent Charity Group shall have sole responsibility for handling requests for additional or supplemental funding from Independent Charity PAPs outside of the annual approved amount and for requesting additional funding and seeking approval from the ELT (or a subset thereof), for donations to Independent Charity PAPs outside of the annual approved amount. Such requests shall be assessed against objective criteria established by the Independent Charity Group. Pfizer legal and compliance personnel shall also be involved in the review and approval of requests for additional or supplemental funding. The purpose of this review shall be to ensure that any

supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and Pfizer policies and procedures.

4. *Criteria Relating to Donations to Independent Charity PAPs.* The Independent Charity Group (with input from the legal and compliance departments) shall establish objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs. The criteria shall be designed to ensure compliance with Federal health care program requirements and OIG guidance.

Pfizer's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the independent charity or over its assistance program. Pfizer shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease fund by the Independent Charity PAP.

Personnel from Pfizer's legal and compliance departments shall review all proposed donations and arrangements between Pfizer and any Independent Charity PAP. Pfizer shall not make any donations to any Independent Charity Group or to any disease state fund of an Independent Charity PAP until after the legal and compliance review has occurred.

Pfizer agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Pfizer does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, Pfizer has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;
- b. Pfizer does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent

Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program;

- c. Pfizer does not and shall not solicit or use any data or information it receives from an Independent Charity PAP (either directly, indirectly, or through third parties) to correlate the amount or frequency of its donations with the Independent Charity PAP's support for Pfizer's products or services; and
- d. Pfizer does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

Pfizer shall continue to maintain the Independent Charity PAP processes described above (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to the process described above.

5. *Independent Charity PAP Review Program.* Within 120 days after the Effective Date, Pfizer shall establish an Independent Charity PAP Review Program (Independent Charity PAP Review Program) through which members of the compliance department or other appropriate personnel (either Pfizer employees or outside resources) (Monitoring Personnel) shall conduct annual monitoring of ten (10) or fifty percent (50%) (whichever is a greater number) of Pfizer's donations to disease state funds of Independent Charity PAPs. The Independent Charity PAP Review Program shall select donations for review through both a risk-based targeting approach and a random sampling approach.

With respect to the donations subject to monitoring, Monitoring Personnel shall review: (a) budget documents; (b) documents relating to the decision to provide donations to a particular Independent Charity PAP; (c) any written agreements in place between Pfizer and the Independent Charity PAPs; (d) correspondence, emails, and other documents reflecting communications and interactions between Pfizer and the Independent Charity PAPs; and (e) other available information relating to the arrangements and interactions between Pfizer and the Independent Charity PAPs. The purpose of the Independent Charity PAP Review Program shall be to assess whether the activities were conducted in a manner consistent with Pfizer's policies and procedures described above and with OIG guidance.

In the event that a compliance issue, including but not limited to any potential improper conduct or noncompliance with Pfizer's policies and procedures or legal or compliance requirements, is identified during any portion of the Independent Charity PAP Review Program, Pfizer shall address the incident consistent with established policies and procedures for the handling of compliance issues. Findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Results from the Independent Charity PAP Review Program, including the identification of potential violations of policies and procedures, shall be compiled and reported to the Compliance Officer for review and follow-up as appropriate. Any compliance issues identified during the PAP Review Program and any corrective action shall be recorded in the files of the Compliance Officer.

Pfizer shall include a summary of the Independent Charity PAP process and the PAP Review Program outlined in this section III.J in the Implementation Report. In addition, Pfizer shall include a description of any changes to the Independent Charity PAP process and the results of the PAP Review Program as part of each Annual Report.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Pfizer proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Pfizer wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Pfizer must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 150 days after the Effective Date, Pfizer shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the RCC who are responsible for satisfying the compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B.3;
6. the Training Plan required by Section III.C.1 and a description of the RCC training required by Section III.C.2 (including a summary of the topics covered in the training for Covered Persons and for the RCC, the length of each type of training, and when the training was provided);
7. (a) a copy of the letter (including all attachments) required by Section III.C.4 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Pfizer's letter;
8. a description of the Risk Assessment and Internal Review Process required by Section III.D;
9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate

that the IRO has the qualifications outlined in Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Pfizer;

10. a description of the Disclosure Program required by Section III.F;

11. a description of the Ineligible Persons screening and removal process required by Section III.G;

12. a description of the Independent Charity PAP process and the Independent Charity PAP Review Program required by Section III.J;

13. a list of all of Pfizer's locations (including locations and mailing addresses but excluding offices operated out of individuals' residences); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

14. a description of Pfizer's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports.

Pfizer shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the RCC, and a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, RCC, and Certifying Employees;

2. the dates of each report made by the Compliance Officer to the RCC (written documentation of such reports shall be made available upon request);

3. the RCC resolution required by Section III.A.3 and a description of the documents and other materials required by the RCC, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
5. a description of any changes to Pfizer's Training Plan developed pursuant to Section III.C and a summary of any RCC training provided during the Reporting Period;
6. (a) a copy of the letter (including all attachments) required by III.C.4 sent to each party employing Third Party Personnel; (b) a list of all entities employing Third Party Personnel with whom Pfizer has entered into such co-promotion and other similar agreements; and (c) a description of the entities' response to Pfizer's letter;
7. a summary of changes to the Risk Assessment and Internal Review Process required by Section III.D, including the reasons for such changes;
8. a summary of the following components of the Risk Assessment and Internal Review Process during the Reporting Period: (a) mitigation plans developed; and (b) steps taken to track the implementation, status, and effectiveness of the mitigation plans. Copies of any mitigation plans, and documents relating to the implementation, status and effectiveness of the mitigation plans shall be made available to OIG upon request.
9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and Pfizer's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
10. a certification from the IRO regarding its professional independence and objectivity with respect to Pfizer;
11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure; (b) the date the disclosure was received; (c) the resolution of the disclosure; and (d) the

date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a summary of any changes to the Independent Charity PAP process or the Independent Charity PAP Review Program outlined in section III.J and the results of the PAP Review Program, including a description of any instances in which it was determined that improper conduct or policy violations occurred and a description of the action(s) that Pfizer took as a result of such determinations;

16. a description of all changes to the most recently provided list of Pfizer's locations (including addresses) as required by Section V.A.13; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees.* In each Annual Report, Pfizer shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise

described in the report, Pfizer is in compliance with the requirements of this CIA; and

- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

3. *Compliance Officer and Chief Executive Officer.* Each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Pfizer is in compliance with the requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. for each disease fund of an Independent Charity PAP to which Pfizer made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Pfizer's policies and procedures (including those outlined in Section III.J); and
- d. for each Pfizer PAP (as defined in Section II.C.4.b above), the facts and circumstances relating to each program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Pfizer's policies and procedures.

D. Designation of Information.

Pfizer shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Pfizer shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Pfizer:

Chief Compliance and Risk Officer
235 East 42nd Street
New York, NY 10017-5755
Tel: (212) 573-2352
Fax: (212) 351-1049

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Pfizer may be

required to provide OIG with an electronic copy of each notification or report required by this CIA in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of or copy Pfizer's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Pfizer's locations for the purpose of verifying and evaluating: (a) Pfizer's compliance with the terms of this CIA and (b) Pfizer's compliance with applicable Federal health care programs requirements. The documentation described above shall be made available by Pfizer to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Pfizer's owners, employees, contractors and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Pfizer shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Pfizer's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Pfizer present.

VIII. DOCUMENT AND RECORD RETENTION

Pfizer shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Pfizer prior to any release by OIG of information submitted by Pfizer pursuant to its obligations under this CIA and identified upon submission by Pfizer as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Pfizer shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Pfizer is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Pfizer and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the RCC compliance obligations;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. training and education of Covered Persons and RCC Members;
- g. a Risk Assessment and Internal Review Process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events; and

1. the Independent Charity PAP processes and Independent Charity PAP Review Program required by Section III.J.
2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to engage and use an IRO as required by Section III.E, Appendix A, or Appendix B.
3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.
4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.
5. A Stipulated Penalty of \$1,500 for each day Pfizer fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Pfizer fails to grant access.)
6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Pfizer as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.
7. A Stipulated Penalty of \$1,000 for each day Pfizer fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Pfizer stating the specific grounds for its determination that Pfizer has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Pfizer shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Pfizer receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. Pfizer may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in

this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Pfizer fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Pfizer receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Pfizer has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Pfizer of: (a) Pfizer's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Pfizer shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Pfizer elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Pfizer cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Pfizer has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Pfizer to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A or Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Pfizer constitutes an independent basis for Pfizer's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Pfizer has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Pfizer of: (a) Pfizer's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Pfizer shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Pfizer has begun to take action to cure the material breach; (ii) Pfizer is pursuing such action with due

diligence; and (iii) Pfizer has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Pfizer fails to satisfy the requirements of Section X.D.3, OIG may exclude Pfizer from participation in the Federal health care programs. OIG shall notify Pfizer in writing of its determination to exclude Pfizer (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Pfizer’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Pfizer may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Pfizer of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Pfizer shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Pfizer was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Pfizer shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related

to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Pfizer to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Pfizer requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Pfizer was in material breach of this CIA and, if so, whether:

- a. Pfizer cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Pfizer's receipt of the Notice of Material Breach:
 - (i) Pfizer had begun to take action to cure the material breach within that period; (ii) Pfizer pursued such action with due diligence; and (iii) Pfizer provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Pfizer, only after a DAB decision in favor of OIG. Pfizer's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Pfizer upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Pfizer may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Pfizer shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Pfizer, Pfizer shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or

regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Pfizer and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Pfizer's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned Pfizer signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PFIZER INC.

/Rady Johnson/

RADY JOHNSON
Executive Vice President
and Chief Compliance and Risk Officer
Pfizer Inc.

May 21, 2018

DATE

/John Rah/

JOHN RAH
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May 22, 2018

DATE

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May 22, 2018

DATE

*Corporate Integrity Agreement
Pfizer Inc.*

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa Re/
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

5-23-18
DATE

/Mary E. Riordan/
MARY E. RIORDAN
Senior Counsel
Office of Counsel to the Inspector General

5/22/18
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. Pfizer shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Pfizer in response to a request by OIG, whichever is later, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

2. If Pfizer engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Pfizer shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Pfizer at the request of OIG, whichever is later, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in Federal health care program requirements (including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act) applicable to the Covered Functions being reviewed;

2. assign individuals to design and select samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program requirements in making assessments in the IRO Review;
3. request clarification from the appropriate authority (e.g., CMS), if in doubt of the application of a particular Federal health care program requirement;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Pfizer and IRO.* If Pfizer terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Pfizer must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Pfizer must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Pfizer in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Pfizer shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Pfizer regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Pfizer in writing that Pfizer shall be required to engage a

new IRO in accordance with Paragraph A of this Appendix. Pfizer must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Pfizer to engage a new IRO shall be made at the sole discretion of OIG.

**CIA with Pfizer Inc.
Appendix B**

I. IRO Engagement, General Description

As specified more fully below, Pfizer shall retain an Independent Review Organization (IRO) to perform engagements to assist Pfizer in assessing and evaluating its systems, processes, policies, and procedures related to Covered Functions as defined in the CIA (IRO Reviews). The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Pfizer may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to Independent Charity PAP Related Functions or the Independent Charity PAP Review Program, the IRO shall perform the Systems Review outlined in Sections II.A.1 and II.B below (relating to Independent Charity PAP Related Functions and the Independent Charity PAP Review Program, respectively) for the first and fourth Reporting Periods.

If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to Pfizer PAPs (as defined in Section II.C.4.b of the CIA), the IRO shall perform the Systems Review outlined in Section II.A.2 below (relating to Pfizer PAPs) for the second and fourth Reporting Periods.

If Pfizer materially changes its systems, processes, policies, and procedures relating to Patient Assistance Related Functions or the Independent Charity PAP Review Program, the IRO shall perform a Systems Review for the Reporting Period(s) in which such material changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

The IRO shall conduct the Transactions Review for the second through fifth Reporting Periods of the CIA.

II. IRO Systems Review

The Systems Review shall be a review of Pfizer's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures)

relating to Patient Assistance Related Functions and the Independent Charity PAP Review Program. Where practical, Pfizer personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Pfizer pursuant to the preceding sentence.

More specifically, the IRO shall review Pfizer's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

A. Patient Assistance Related Functions

- 1) Pfizer's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs.

This review shall include an assessment of the following:

- a. Pfizer's organizational structure as it relates to arrangements and interactions with Independent Charity PAPS, including:
 - i. the identification of those individuals, departments, or groups within Pfizer (e.g., the Independent Charity Group, legal, compliance) that have responsibility for, or involvement with, such arrangements and interactions;
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
 - iii. the identification of those individuals, departments, or groups within Pfizer (e.g., the commercial business units) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
 - iv. methods that Pfizer uses to separate Independent Charity PAP-related responsibilities from the commercial business units.
- b. Pfizer's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:

- i. the criteria governing whether and under what circumstances Pfizer would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
 - ii. communications (including any limitations on such communications) between any representatives of Pfizer and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
 - iii. communications (including any limitations on such communications) between those individuals, departments, or groups within Pfizer with responsibility for Independent Charity PAPs and the commercial business units of Pfizer (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
 - iv. communications (including any limitations on such communications) between representatives of Pfizer and health care providers or patients regarding assistance available through any Independent Charity PAP.
- c. Pfizer's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.3 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
- d. Pfizer's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to a particular Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);
- e. Pfizer's policies and practices as they relate to donations made by Pfizer to any Independent Charity PAPs as referenced in Section III.J.4, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
- f. Pfizer's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Pfizer's products.

- 2) Pfizer's systems, policies, processes, and procedures relating to any Pfizer PAPs.

This review shall include an assessment of the following:

- a. The general elements of Pfizer PAPs, including: i) the types of assistance that are made available through Pfizer PAPs; ii) the types of patients to whom each type of assistance is made available; iii) the eligibility criteria for the various types of assistance provided; and iv) the controls used to implement the eligibility criteria (i.e., controls employed to ensure that appropriate patients receive the various types of assistance);
- b. Pfizer's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to provide (or continue to provide) the various types of assistance through any Pfizer PAP; and ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount); and
- c. Pfizer's policies and practices as they relate to any contracts or agreements entered between Pfizer and outside entities relating to any Pfizer PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or agreements, and the review and approval of such contracts or agreements.

B. Independent Charity PAP Review Program

- 1) Pfizer's systems, policies, processes, and procedures related to its Independent Charity PAP Review Program.

This review shall include a review to understand the following:

- a. Pfizer's systems, processes, policies and procedures related to Pfizer's Independent Charity PAP Review Program required by Section III.J.5 that are designed to identify and manage relevant risks arising under Federal health care program requirements associated with donations by pharmaceutical manufacturers to Independent Charity PAPs;
- b. The process or factors that Pfizer uses to identify the following:

- i. which donation arrangements with Independent Charity PAPs will be reviewed for the particular Reporting Period;
 - ii. the relevant Pfizer colleague roles that Pfizer will include in the Independent Charity PAP Review Program for a particular Reporting Period; and
 - iii. the relevant records, documents or other information that Pfizer will include as part of its Independent Charity PAP Review Program for a particular Reporting Period;
- c. The frequency or timing of when Pfizer conducts the Independent Charity PAP Review Program;
- d. The experience and background of individuals who are engaged in the Independent Charity PAP Review Program and a review of any relevant training or other guidance provided to these individuals; and
- e. The systems, policies, processes and procedures to review initial results of the Independent Charity PAP Review Program that are related to donations to Independent Charity PAPs and to remediate any issues identified as a part of the Independent Charity PAP Review Program.

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review.

A. Independent Charity PAP Related Functions

For each of the Reviewed Policies and Procedures identified in Section II.A.1 above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Pfizer's systems, policies, processes, and procedures relating to the items identified in Section II.A.1 above, including a general description of Pfizer's control and accountability systems (e.g., documentation

- and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.A.1 above are made known or disseminated within Pfizer;
 - 4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP and the donations or other assistance provided in response to such requests;
 - 5) findings and supporting rationale regarding any weaknesses in Pfizer's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
 - 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

B. Pfizer PAPs

For each of the Reviewed Policies and Procedures identified in Section II.A.2 above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Pfizer's systems, policies, processes, and procedures relating to the items identified in Section II.A.2 above, including a general description of Pfizer's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.2 above are made known or disseminated within Pfizer;
- 4) a detailed description of any system(s) used to track donations or other assistance provided in response to requests through any Pfizer PAP;
- 5) findings and supporting rationale regarding any weaknesses in Pfizer's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

- 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

C. Independent Charity PAP Review Program

For each of the systems, processes, policies and procedures reviewed pursuant to Section II.B above, the report shall include the following items:

- 1) A description of the documentation reviewed and personnel interviewed as part of the Independent Charity PAP Review Program Systems Review;
- 2) A description of the systems, processes, policies and procedures that Pfizer uses to conduct the Independent Charity PAP Review Program and to remediate and escalate issues related to donations to Independent Charity PAPs;
- 3) A description of the background and experience of the individuals who perform the Independent Charity PAP Review Program;
- 4) Whether the Independent Charity PAP Review Program processes, policies and procedures related to the Independent Charity PAP Review Program are reasonably designed to identify, prioritize and manage relevant risks;
- 5) Whether the systems, processes, policies and procedures are reasonably designed to escalate identified issues and/or remediate such issues;
- 6) Recommendations to improve any of the systems, policies, processes, or procedures relating to the Independent Charity PAP Review Program, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of Pfizer's arrangements with selected Independent Charity PAPs; and (2) a review of up to three additional items identified by OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Arrangements with Independent Charity PAPs

The IRO shall conduct a review and assessment of Pfizer's compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.J of the CIA. More specifically, the IRO shall review fifty percent (50%) of the donation arrangements that Pfizer entered into with Independent Charity PAPs during the Reporting Period for which the IRO is conducting the Transactions Review.

As a matter of practice, Pfizer enters a separate agreement with an Independent Charity PAP for each disease state fund of the PAP to which Pfizer makes a donation. Pfizer shall provide the IRO with a list of all Independent Charity PAPs with which Pfizer entered into a donation agreement during the Reporting Period under review (the applicable Reporting Period.) The IRO will randomly select and review 50% of these donation arrangements for the applicable Reporting Period.

For purposes of the Independent Charity PAP Transactions Review, the term "Reviewed Materials" shall mean the following for each Independent Charity PAP arrangement reviewed:

- 1) the Annual Notice from Pfizer to Independent Charity PAPs (which announces Pfizer's willingness to consider written requests for contributions and seeks information regarding anticipated patient need for particular disease state funds; patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs);
- 2) responses from Independent Charity PAPs to the Annual Notice (which includes information on anticipated patient need for particular disease state funds; details regarding patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs (e.g., information about administrative fees, patient grant amounts, average processing time to assist patients, etc.));
- 3) patient needs assessment documentation related to a donation arrangement with an Independent Charity PAP (which includes information on the assessment of patient need in disease states based on non-patient-specific or drug-specific information from eligible Independent Charity PAPs, other publicly available information, and Pfizer's internal free drug program);

- 4) allocation documentation that shows the objective criteria used to evaluate Independent Charity PAPs and the allocation of the approved budget across disease states and Independent Charity PAPs (e.g., patient needs assessment information for disease state funds, information about Pfizer's historical donations; eligibility criteria of the Independent Charity PAPs; and other relevant information, as applicable);
- 5) documents regarding donations to Independent Charity PAPs required by Pfizer policy to evidence or document the review and approval of a decision to provide a donation to a particular fund of an Independent Charity PAP (i.e., minutes from Pfizer's Independent Charity PAP Review Committee that memorialize donation decisions, including budget allocation across disease states and Independent Charity PAPs, and final determinations (approvals or rejections) on proposed donations to Independent Charity PAPs);
- 6) to the extent not covered by item 2 above, all correspondence between Pfizer and an Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP;
- 7) any donation agreement entered into between Pfizer and an Independent Charity PAP during the relevant Reporting Period; and
- 8) payment documentation required by Pfizer policy reflecting: a) the total amount of donations Pfizer agreed to make to an Independent Charity PAP broken down by disease fund, if applicable; b) the schedule of such payments, if applicable; c) the actual payments made; and d) any decisions to change the initial donation amount agreed to by Pfizer.

For each Independent Charity PAP donation arrangement selected as part of the IRO review, the IRO shall assess the Reviewed Materials to evaluate whether the Independent Charity PAP Related Functions were conducted in a manner consistent with Pfizer's policies and procedures, including those described in Section III.J of the CIA, and with OIG guidance. In addition, the IRO may interview members of Pfizer's Independent Charity Group regarding the Reviewed Materials and Pfizer's policies and process relating to donations to Independent Charity PAPs.

Based upon the Reviewed Materials and any interviews of the Independent Charity Group, the IRO shall evaluate and identify:

- 1) Whether activities relating to arrangements with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Pfizer in accordance with the company's policies and procedures including those outlined in Section III.J.1 of the CIA;
- 2) Whether Pfizer's commercial business units influenced or were involved in the Independent Charity Group's decisions to enter into an arrangement with an Independent Charity PAP in violation of Pfizer's policies and procedures or OIG guidance;
- 3) Whether Pfizer followed the budgeting policies and practices outlined in Section III.J.3 of the CIA with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- 4) Whether Pfizer followed the decision-making and approval process required by Pfizer's policies and procedures and outlined in Section III.J of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether Pfizer would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- 5) Whether Pfizer followed the policies and practices outlined in Section III.J.4 in connection with all donations made by Pfizer to any Independent Charity PAP, including as they pertain to the internal review of potential donations and adherence to the criteria set forth in Section III.J.4;
- 6) Any communications that occurred between any representatives of Pfizer and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with Pfizer's policies and procedures and OIG guidance;
- 7) Whether for each donation made to the Independent Charity PAP, Pfizer complied with the requirements outlined in Section III.J.4; and
- 8) Whether, based on its review, the IRO found that Pfizer exerted influence or control over the Independent Charity PAP in violation of Pfizer's policies and procedures, including those outlined in Section III.J.4.

B. IRO Review of Additional Items

As set forth in Section III.E.2 of the CIA, for each Reporting Period OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). The Additional Items may include activities undertaken by Pfizer in connection with Promotional Functions, as defined in Section III.C.3 of the CIA. The Additional Items Review could also include activities undertaken by Pfizer in connection with any Pfizer PAP, including the provision of free product to patients.

No later than 150 days prior to the end of the applicable Reporting Period, OIG shall notify Pfizer of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO shall submit an audit work plan to OIG for approval.

The IRO shall conduct the review of the Additional Items based on a work plan approved by OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in Pfizer’s systems, processes, policies, and procedures based on its review of each Additional Item).

Pfizer may propose to OIG that relevant internal audit(s) or monitoring and/or other reviews conducted by outside entities at Pfizer’s request be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO for the applicable Reporting Period. OIG retains sole discretion over whether, and in what manner, to allow Pfizer’s internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the Additional Items review conducted by the IRO.

If OIG denies Pfizer’s request to permit its internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the IRO’s review of Additional Items in a given Reporting Period, Pfizer shall engage the IRO to perform the Review as outlined in this Section IV.B. If OIG agrees to permit certain of Pfizer’s internal audit work or other reviews for a given Reporting Period to be substituted for a portion of an Additional Items review, such work or reviews may be subject to verification by the IRO (Verification Review). In such an instance, OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

Pfizer Inc.
Appendix B to CIA

1. General Elements to Be Included in Report

- a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2. Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(for the review of Independent Charity PAP arrangements)

- a) a list of the Independent Charity PAP funds to which Pfizer made donations during the Reporting Period;
- b) for each Independent Charity PAP arrangement reviewed by the IRO, a description of the review conducted by IRO;
- c) for each Independent Charity PAP arrangement reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-8;
- d) for each Independent Charity PAP arrangement reviewed by the IRO, a statement as to whether Pfizer identified any compliance issues associated with the arrangement;
- e) the findings and supporting rationale regarding any overall weaknesses in Pfizer's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
- f) recommendations, if any, for changes in Pfizer's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.

(Relating to the Review of Additional Items)

- a) for each Additional Item reviewed, a description of the review conducted;
- b) for each Additional Item reviewed, the IRO's findings based on its review;
- c) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Pfizer's systems, processes, policies, procedures, and practices relating to the Additional Item; and
- d) for each Additional Item reviewed, recommendations, if any, for changes in Pfizer's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.



THE UNITED STATES ATTORNEY'S OFFICE
DISTRICT *of* MASSACHUSETTS

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U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

Wednesday, July 1, 2020

Novartis Agrees to Pay Over \$51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations

BOSTON – Novartis Pharmaceuticals Corporation (Novartis) has agreed to pay \$51.25 million to resolve allegations that it violated the False Claims Act by illegally paying the Medicare co-pays for its own drugs.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, co-pays). Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

"According to the allegations in today's settlement, Novartis coordinated with three co-pay foundations to funnel money through the foundations to patients taking Novartis' own drugs," said United States Attorney Andrew E. Lelling. "As a result, the Novartis' conduct was not 'charitable,' but rather functioned as a kickback scheme that undermined the structure of the Medicare program and illegally subsidized the high costs of Novartis' drugs at the expense of American taxpayers. At the same time, we recognize that Novartis' current management has taken constructive steps to address the government's concerns with the company's prior relationships with co-pay foundations."

"Through this settlement and others, the government has demonstrated its commitment to ensuring that drug companies do not use kickbacks to influence the drugs prescribed by doctors or purchased by patients," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "We will continue to safeguard the Medicare program from kickbacks and their pernicious effects, including the undermining of important cost-control mechanisms instituted by Congress."

"Improper coordination between pharmaceutical manufacturers and foundations operating patient assistance programs harms Medicare by increasing costs and distorting the prescription drug market," said Gregory E. Demske, Chief Counsel to the Inspector General. "This CIA promotes independence in those relationships and accountability on the part of manufacturer Boards of Directors and senior management."

"Novartis tried to game the system to boost its bottom line at the expense of sick patients facing economic hardship, and the hard-working taxpayers who fund the Medicare program," said Joseph R. Bonavolonta,

PFE000536

Special Agent in Charge of the FBI Boston Division. “Today’s settlement is a warning to all pharmaceutical companies that if they pay kickbacks, like Novartis did in this case, our health care fraud task force will do everything it can to make sure they are held accountable.”

The government’s allegations in the settlement announced today are as follows:

At certain intervals during the period from Jan. 1, 2010, through Dec. 31, 2014, Novartis used The Assistance Fund (TAF) as a conduit to pay kickbacks to Medicare patients taking Gilenya, a Novartis drug for multiple sclerosis (MS), and used the National Organization for Rare Disorders (NORD) and Chronic Disease Fund (CDF) as conduits to pay kickbacks to Medicare patients taking Afinitor, a Novartis drug for renal cell carcinoma (RCC) and progressive neuroendocrine tumors of pancreatic origin (PNET).

With respect to TAF, in October 2012, Novartis learned from Express Scripts, which then was managing Novartis’ free drug program for Gilenya, that Novartis was providing free Gilenya to 364 patients who would become eligible for Medicare the following year. Novartis and Express Scripts transitioned these patients to Medicare Part D so that, in the future, Novartis would obtain revenue from Medicare when the patients filled their prescriptions for Gilenya. Knowing that these patients could not afford co-pays for Gilenya, Novartis developed a plan for it to cover their co-pays through TAF, which operated a fund that, ostensibly, offered to cover co-pays for any MS patient who met TAF’s financial eligibility criteria, regardless of which MS drug the patient was taking. Specifically, just after it made a payment to TAF, Novartis arranged for TAF to open its MS fund at 6:00 p.m. on Friday, Dec. 14, 2012, and for Express Scripts to have personnel working overtime that night and the following morning submitting applications to TAF on behalf of patients who previously had been receiving free Gilenya from Novartis. Novartis knew that the timing of the opening of the fund and the readiness of Express Scripts to submit applications on behalf of Gilenya patients at that time would result in Gilenya patients receiving a disproportionate share of the grants from the fund while it was open. After the fund closed on Saturday, Dec. 15, 2012, Novartis confirmed that, during the brief period the fund had been open, TAF used Novartis’ money to provide 374 Gilenya patients with grants to cover their Medicare co-pays in 2013. Novartis subsequently made further payments to TAF, and TAF provided many of these same Gilenya patients with grants to cover their Medicare co-pays in 2014.

With respect to NORD, Novartis learned that, as of the 2010 donation year, no other manufacturer of RCC medications would be contributing to a pre-existing NORD RCC co-pay assistance fund. Novartis knew that Afinitor was approved for use as a second-line RCC treatment only, and only when certain first-line products had failed. Novartis also knew, therefore, that any co-pays NORD covered for initial RCC treatments would not be used to cover co-pays for Afinitor. Novartis informed NORD that it would be willing to donate to its RCC fund if NORD narrowed the fund’s eligibility definition so as not to cover co-pays for first line treatments. Novartis wanted the definition narrowed to ensure that a greater amount of its donations would subsidize its product, as opposed to others. NORD then created a new fund entitled “Advanced Renal Cell Carcinoma Second Line Co-Payment Assistance Program.” This fund excluded any patients seeking co-pay coverage for first-line RCC treatments and disproportionately funded patients taking Afinitor compared to its overall usage rate among all RCC drugs. Novartis financed this NORD fund through 2014.

With respect to CDF, in 2012, after Afinitor was approved to treat PNET, Novartis asked CDF to open a fund to cover Afinitor co-pays for PNET patients. At that time, Novartis knew that the FDA had approved a competing drug to treat PNET. Nonetheless, with Novartis’ knowledge, CDF launched a fund labeled “PNET” that covered co-pays only for Afinitor and did not cover co-pays for the other PNET drug. Novartis continued with this understanding as the sole financial backer of this supposed “PNET” fund through 2014.

Novartis entered into a five-year corporate integrity agreement (CIA) with OIG as part of this settlement and a simultaneous settlement being announced today by the United States Attorney’s Office for the Southern District of New York. The CIA requires Novartis to implement measures, controls, and monitoring designed to promote independence from any patient assistance programs that it finances. In addition, Novartis agreed

to implement risk assessment programs and to obtain compliance-related certifications from company executives and Board members.

To date, the Department of Justice has collected over \$900 million from ten pharmaceutical companies (United Therapeutics, Pfizer, Actelion, Jazz, Lundbeck, Alexion, Astellas, Amgen, Sanofi, and Novartis) that allegedly used third-party foundations as kickback vehicles. The Department also has reached settlements with four foundations (Patient Access Network Foundation, Chronic Disease Fund, The Assistance Fund, and Patient Services, Inc.) that allegedly conspired or coordinated with these pharmaceutical companies.

U.S. Attorney Lelling, Assistant Attorney General Hunt, HHS Chief Counsel to the Inspector General Demske, and FBI Boston SAC Bonavolonta made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling's Affirmative Civil Enforcement Unit, and by Trial Attorneys Sarah Arni and Augustine Ripa of the Justice Department's Civil Division.

Attachment(s):

[Download Novartis Settlement Agreement.pdf](#)

Topic(s):

Health Care Fraud

Component(s):

[USAO - Massachusetts](#)

Updated July 1, 2020



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FOR IMMEDIATE RELEASE

Friday, February 28, 2020

Sanofi Agrees to Pay \$11.85 Million to Resolve Allegations That it Paid Kickbacks Through a Co-Pay Assistance Foundation

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical company Sanofi-Aventis U.S., LLC ("Sanofi"), has agreed to pay \$11.85 million to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation, The Assistance Fund ("TAF").

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively "co-pays"). These co-pay obligations may be substantial for expensive medications. Congress included co-pay requirements in the Medicare program, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

Sanofi sells Lemtrada, a multiple sclerosis drug that costs nearly \$100,000 per patient per year. Medicare co-pays for Lemtrada can be many thousands of dollars per year. The cost of the drug often presents significant barriers to access for Medicare patients.

The government alleged that TAF, an entity claiming 501(c)(3) status for tax purposes, operates funds, including a fund for MS patients, that pay the co-pays of certain patients, including Medicare patients, who were prescribed Lemtrada. TAF allegedly raised its maximum per-patient grant allocation to \$20,000 specifically to accommodate Lemtrada patients. During the relevant time period, TAF's MS fund frequently ran out of funding and was closed to new patients. If any patients applied for co-pay assistance at a time when the MS fund was out of funding and closed to new patients, TAF did not maintain a wait list of such patients. As a consequence, whenever TAF's MS fund opened to new patients, the fund provided grants to the patients who applied immediately after the opening and did not provide grants to patients who had sought to apply earlier but at a time when the fund was closed.

The United States further alleged that Sanofi made payments to TAF not with a charitable purpose but rather with the intention of using TAF as a conduit to pay the financial obligations, including Medicare co-pay obligations, of patients taking Lemtrada, and that Sanofi's payment through TAF of Medicare co-pays for

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Lemtrada violated the Anti-Kickback Statute. To effectuate its scheme, Sanofi worked with its third-party reimbursement hub to identify Medicare patients for whom physicians had prescribed Lemtrada, but who had not yet received infusions of the drug because they lacked sufficient funds to afford the co-pays for Lemtrada. Sanofi made nine payments to TAF during 2015 and 2016. At the times Sanofi made eight of these nine payments, TAF's MS fund had run out of funding, and was closed to new patients. In conjunction with its payments to TAF, and knowing that TAF's MS fund did not maintain wait lists and would fund the first patients who applied for assistance after the fund received new funding, Sanofi instructed its hub quickly to refer as many Lemtrada patients as possible to the TAF MS fund. As a result, when TAF's MS fund opened with funding from Sanofi, Lemtrada patients received a disproportionately large share of the Medicare co-pay grants TAF issued and patients taking MS drugs other than Lemtrada received a disproportionately small share of the Medicare co-pay grants TAF issued.

"According to the allegations in today's settlement agreement, Sanofi used a supposed charity as a conduit to funnel money to patients taking Sanofi's very expensive drug, all at the expense of the Medicare program," said United States Attorney Andrew E. Lelling. "This office will continue to pursue drug companies for violations of the anti-kickback laws. We commend Sanofi for swiftly resolving the government's allegations."

"Sanofi sought to undermine the Medicare program through its use of kickbacks disguised as routine charitable donations aimed at helping patients battling multiple sclerosis and who were struggling with costly copays," said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. "They rigged the system so those taking its drug Lemtrada gained an unfair advantage over patients using other medications, and with today's settlement, they are finally being held accountable for their actions."

Sanofi has also entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA requires, among other things, that Sanofi implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, and compliance-related certifications from company executives and Board members.

A limited liability partnership formed by a former employee of Sanofi's predecessor, Genzyme Corporation, brought these allegations through a whistleblower lawsuit. Under the *qui tam* provisions of the False Claims Act, private individuals, known as relators, can sue on behalf of the government for false claims and share in any recovery. In connection with today's announced settlement, the partnership will receive approximately \$2.7 million of the recovery.

U.S. Attorney Lelling, HHS-OIG Chief Counsel Demske and FBI SAC Joseph Bonavolonta made the announcement today. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Evan Panich of Lelling's Office, with assistance from Kelley Hauser, Trial Attorney with Department of Justice's Civil Division.

Topic(s):

Health Care Fraud

Component(s):

USAO - Massachusetts

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FOR IMMEDIATE RELEASE

Thursday, April 25, 2019

Two Pharmaceutical Companies Agree to Pay a Total of Nearly \$125 Million to Resolve Allegations that they Paid Kickbacks Through Co-Pay Assistance Foundations

BOSTON – The U.S. Attorney's Office announced today that two pharmaceutical companies – Astellas Pharma US, Inc. (Astellas), and Amgen Inc. (Amgen) – have agreed to pay a total of \$124.75 million to resolve allegations that they violated the False Claims Act by illegally paying the Medicare co-pays for their own high-priced drugs.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, co-pays). Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

"According to the allegations in today's settlements, Astellas and Amgen conspired with two co-pay foundations to create funds that functioned almost exclusively to benefit patients taking Astellas and Amgen drugs," said United States Attorney Andrew E. Lelling. "As a result, the companies' payments to the foundations were not 'donations,' but rather were kickbacks that undermined the structure of the Medicare program and illegally subsidized the high costs of the companies' drugs at the expense of American taxpayers. We will keep pursuing these cases until pharmaceutical companies stop engaging in this kind of behavior."

"When pharmaceutical companies use foundations to create funds that are used improperly to subsidize the copays of only their own drugs, it violates the law and undercuts a key safeguard against rising drug costs," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "These enforcement actions make clear that the government will hold accountable drug companies that directly or indirectly pay illegal kickbacks."

"Kickback schemes can undermine our healthcare system, compromise medical decisions, and waste taxpayer dollars," said Phillip Coyne, Special Agent in Charge, Office of the Inspector General of the Department of Health and Human Service's Boston Regional Office. "We will continue to hold

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pharmaceutical companies accountable for subverting the charitable donation process in order to circumvent safeguards designed to protect the integrity of the Medicare program.”

“As today’s settlements make clear, the FBI will aggressively go after pharmaceutical companies that look to bolster their drug prices by paying illegal kickbacks--whether directly or indirectly--to undermine taxpayer funded healthcare programs, including Medicare,” said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division.

The government’s allegations in the two settlements announced today are as follows:

Astellas. Astellas sells Xtandi, an androgen receptor inhibitor (ARI) drug used to treat metastatic castration resistant prostate cancer (mCRPC) in patients who have failed chemotherapy. While there are other mCRPC drugs, none of the other major mCRPC drugs is an ARI. The government alleges that, during the period from July 2013 through December 2014, Astellas arranged for two foundations to operate ARI funds that covered mCRPC patients’ co-pays for ARIs, but not for other mCRPC drugs, and that Xtandi patients received nearly all of the assistance from these two funds. The government further alleges that, during the time that the ARI funds were open, Astellas promoted the existence of the ARI funds as an advantage for Xtandi over competing mCRPC drugs in an effort to persuade medical providers to prescribe Xtandi. During this period, Astellas raised the price of Xtandi at over 24 times the rate of overall inflation in the United States. Astellas has agreed to pay \$100 million to resolve the government’s allegations.

Amgen. Amgen sells Sensipar, a treatment for secondary hyperparathyroidism (SHPT), and Kyprolis, a treatment of multiple myeloma. The government alleges that, in late 2011, Amgen stopped donating to a foundation that covered co-pays for patients taking any of several SHPT drugs and approached a new foundation about creating a fund that would cover only Sensipar patients’ Medicare co-pays. Amgen thereafter paid millions of dollars to this fund. Until June 2014, the fund helped only Sensipar patients, as Amgen had requested. Amgen allegedly covered the co-pays of Sensipar patients through this fund even though the cost of doing so exceeded the cost Amgen would have incurred by providing free Sensipar to the same patients. By enabling the fund to cover the copays of Medicare beneficiaries, Amgen caused claims to be submitted to Medicare and generated revenue for itself. During the period the fund covered only Sensipar, Amgen raised the price of Sensipar at over four times the rate of overall inflation in the United States.

The government further alleges that Amgen’s predecessor, Onyx Pharmaceuticals Inc. (Onyx), asked a different foundation to create a fund that, ostensibly, would cover health care related travel expenses for patients taking any multiple myeloma drug, but that, as Onyx and the foundation both knew, functioned almost exclusively to cover travel expenses for patients taking Kyprolis. The foundation also operated a second fund that covered co-pays for several multiple myeloma drugs, including Kyprolis. The government alleges that, for 2013, Onyx obtained data from the foundation on the multiple myeloma fund’s anticipated and actual expenses for coverage only of Kyprolis co-pays. Onyx then donated to the fund in an amount Onyx understood to be sufficient only to cover the co-pays of Kyprolis patients. Amgen has agreed to pay \$24.75 million to resolve the government’s allegations.

Amgen and Astellas each entered five-year corporate integrity agreements (CIAs) with OIG as part of their respective settlements. The CIAs require the companies to implement measures, controls, and monitoring designed to promote independence from any patient assistance programs to which they donate. In addition, the companies agreed to implement risk assessment programs and to obtain compliance-related certifications from company executives and Board members.

To date, the Department of Justice has collected over \$840 million from eight pharmaceutical companies (United Therapeutics, Pfizer, Actelion, Jazz, Lundbeck, Alexion, Astellas, and Amgen) that allegedly used third-party foundations as kickback vehicles. The U.S. Attorney’s Office for the District of Massachusetts initiated each of these investigations.

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U.S. Attorney Lelling, Assistant Attorney General Hunt, HHS-OIG SAC Coyne, and FBI SAC Bonavolonta made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling's Affirmative Civil Enforcement Unit, and by Trial Attorneys Augustine Ripa and Sarah Arni of the Justice Department's Civil Division.

Attachment(s):

[Download Amgen Settlement Agreement .pdf](#)

[Download Astellas Settlement Agreement.pdf](#)

Topic(s):

Health Care Fraud

Component(s):

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Updated April 25, 2019



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FOR IMMEDIATE RELEASE

Thursday, April 4, 2019

Three Pharmaceutical Companies Agree to Pay a Total of Over \$122 Million to Resolve Allegations that they Paid Kickbacks Through Co-Pay Assistance Foundations

BOSTON – The U.S. Attorney's Office announced today that three pharmaceutical companies –Jazz Pharmaceuticals plc (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals, Inc. – have agreed to pay a total of \$122.6 million to resolve allegations that they violated the False Claims Act by paying kickbacks to Medicare and Civilian Health and Medical Program (ChampVA) patients through purportedly independent charitable foundations.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, co-pays). Similarly, under ChampVA, patients may be required to pay a co-pay for medications. Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can set for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare or VA patients to purchase the companies' drugs.

"We are committed to ensuring that pharmaceutical companies do not use third-party foundations to pay kickbacks masking the high prices those companies charge for their drugs," said United States Attorney Andrew E. Lelling. "This misconduct is widespread, and enforcement will continue until pharmaceutical companies stop circumventing the anti-kickback laws to artificially bolster high drug prices, all at the expense of American taxpayers."

"Pharmaceutical companies undercut a key safeguard against rising drug costs when they create assistance funds to serve as conduits for the companies to subsidize the copays of their own drugs," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "These enforcement actions make clear that the government will hold accountable drug companies that directly or indirectly pay illegal kickbacks."

"These settlements demonstrate the FBI's commitment to safeguarding the Medicare program and ensuring that patients receive treatment solely based on their medical needs," said Joseph R. Bonavolonta, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. "Not only did these

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companies undermine a program that was set up to assist patients in decreasing the cost of their drugs, but they threatened the financial integrity of the Medicare program to which we all contribute and on which we all depend.”

“Kickback schemes undermine the integrity our nation’s healthcare system, including healthcare benefits administered by the U.S. Department of Veterans Affairs,” said Special Agent-in-Charge Sean Smith, VA Office of Inspector General, Northeast Field Office. “The VA Office of Inspector General, along with our law enforcement partners, will continue to aggressively pursue these investigations and exhaust all efforts to uncover these schemes.”

The government’s allegations in the three settlements announced today are as follows:

Jazz. Jazz sells Xyrem, a treatment for narcolepsy, and Prialt, a non-opioid treatment for management of severe chronic pain. The government alleges that, in 2011, Jazz asked a foundation to create a fund that would cover the co-pays of Xyrem patients. The foundation then created a fund that would ostensibly cover the co-pays of patients taking any narcolepsy drug, but that, through May 2014, almost exclusively assisted patients taking Xyrem. During this period, Jazz raised the price of Xyrem at over 24 times the rate of overall inflation in the United States. The government further alleges that Jazz asked the same foundation to create a fund that would purportedly cover the co-pays of patients taking any drug for severe chronic pain, but that, through May 2014, almost exclusively assisted patients taking Prialt. The foundation told Jazz that, when severe chronic pain patients seeking assistance with drugs other than Prialt contacted the foundation, the foundation would refer them elsewhere. Furthermore, as Jazz knew, the foundation did not advertise the severe chronic pain fund on its website, so that Jazz itself was the principal source referrals to the fund. Jazz has agreed to pay \$57 million to resolve the government’s allegations.

Lundbeck. Lundbeck sells Xenazine, a treatment for chorea associated with Huntington’s Disease. The government alleges that, beginning in 2011, Lundbeck donated millions of dollars to a foundation’s fund that, ostensibly, covered the co-pays of patients with Huntington’s Disease, but that, in fact, simply covered the co-pays of patients taking Xenazine, regardless of the condition the drug was being used to treat. After May 2014, when HHS-OIG published a document entitled “Supplemental Special Advisory Bulletin: Independent Charity Assistance Programs,” Lundbeck and the foundation agreed that the foundation would continue to pay the Xenazine co-pays for non-Huntington’s Disease patients out of a “general fund” that the foundation would use for this purpose. When Lundbeck asked the foundation whether there was a “risk” that HHS-OIG would not view this practice as compliant, the foundation replied, “[t]hey don’t know what we use the general fund for.” This conduct continued through 2016. During the period of the alleged misconduct, Lundbeck raised the price of Xenazine at over 22 times the rate of overall inflation in the United States. Lundbeck has agreed to pay \$52.6 million to resolve the government’s allegations.

Jazz and Lundbeck each entered five-year corporate integrity agreements (CIAs) with OIG as part of their respective settlements. The CIAs require the companies to implement measures, controls, and monitoring designed to promote independence from any patient assistance programs to which they donate. In addition, the companies agreed to implement risk assessment programs and to obtain compliance-related certifications from company executives and Board members.

“These kickback schemes harm Medicare and the public,” said Gregory E. Damske, Chief Counsel to the Inspector General. “OIG CIAs, such as those with Jazz and Lundbeck, are designed to reduce future risks to patients and taxpayer-funded programs. OIG decided not to require a CIA with Alexion because it made sweeping and fundamental organizational changes following the bad conduct. The changes included hiring a new eight-member executive leadership team and changing half of the members of its Board of Directors. In addition, forty percent of Alexion’s employees are new and the company relocated its corporate headquarters.”

Alexion. Alexion sells Soliris, a drug that is approved to treat patients with paroxysmal nocturnal hemoglobinuria (PNH) and to treat patients with atypical hemolytic uremic syndrome (aHUS). Soliris can cost over \$500,000 per year. Alexion allegedly knew that the price it set for Soliris could pose a financial burden to patients. In January 2010, the government alleges, Alexion requested that a foundation create a “Complement-Mediated Disease” (“CMD”) fund. Over the next several months, Alexion and the foundation allegedly discussed the coverage parameters that Alexion desired for the fund, including Alexion’s desire that the fund “not support a patient with any of these [CMD] diagnoses for other reasons tha[n] Soliris therapy.” The government alleges that, after the fund opened, Alexion—the sole donor to the fund—understood that the fund’s provision of financial assistance to a patient was contingent on the patient taking Soliris. Alexion allegedly noted internally that it needed to be diligent in notifying the foundation if a patient had stopped taking Soliris so that Alexion’s donations would not be used on patients who were not starting or maintaining Soliris therapy. Alexion has agreed to pay \$13 million to resolve the government’s allegations.

U.S. Attorney Lelling, Assistant Attorney General Hunt, HHS-OIG Chief Counsel Demske, FBI SAC Bonavolonta, and VA OIG SAC Sean Smith made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling’s Affirmative Civil Enforcement Unit, and by Trial Attorneys Augustine Ripa and Sarah Arni of the Justice Department’s Civil Division.

Attachment(s):

[Download Alexion_Settlement.pdf](#)

[Download Jazz_Settlement.pdf](#)

[Download Lundbeck_Settlement.pdf](#)

Topic(s):

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Component(s):

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Updated April 4, 2019



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FOR IMMEDIATE RELEASE

Thursday, December 6, 2018

Actelion Pharmaceuticals Agrees to Pay \$360 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical company Actelion Pharmaceuticals US, Inc. (Actelion), a seller of pulmonary arterial hypertension (PAH) drugs, has agreed to pay \$360 million to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively "co-pays"). These co-pay obligations may be substantial for expensive medications. Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

Actelion sells a number of PAH drugs, including Tracleer, Ventavis, Veletri, and Opsumit. As part of today's settlement, the government alleged that Actelion used a foundation as a conduit to pay the co-pay obligations of thousands of Medicare patients taking Actelion's PAH drugs. By doing so, the government alleged, Actelion was able to induce patients to purchase its drugs when the prices Actelion had set for those drugs otherwise could have posed a barrier to purchases.

The government alleges that in 2014 and 2015, Actelion routinely obtained data from the foundation detailing how many patients on each Actelion drug the foundation had assisted, how much the foundation had spent on those patients, and how much the foundation expected to spend on those patients in the future. Actelion used this information to budget for future payments to the foundation on a drug-specific basis and to confirm that its contribution amounts to the foundation were sufficient to cover the copays of patients taking Actelion's drugs, but not of patients taking other manufacturers' PAH drugs. Actelion engaged in this practice even though the foundation warned the company against receiving data concerning the foundation's expenditures on copays for Actelion's drugs. Meanwhile, the government also alleged that Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays for Actelion's drugs.

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Instead, to generate revenue from Medicare and induce purchases of its drugs, the government alleged that Actelion referred such Medicare patients to the foundation, which allowed the patients' copays to be paid and resulted in claims to Medicare for the remaining cost.

"Using data from a foundation that it knew it should not have, Actelion effectively set up a proprietary fund to cover the co-pays of just its own drugs," said United States Attorney Andrew E. Lelling. "Such conduct not only violates the anti-kickback statute, it also undermines the Medicare program's co-pay structure, which Congress created as a safeguard against inflated drug prices. During the period covered by today's settlement, Actelion raised the price of its main PAH drug, Tracleer, by nearly 30 times the rate of overall inflation in the United States."

"This settlement, as do prior settlements concerning similar misconduct, make clear that the government will hold accountable drug companies that pay illegal kickbacks," said Assistant Attorney General Joseph H. Hunt of the Department Justice's Civil Division. "Pharmaceutical companies cannot have it both ways—they cannot continue to increase drug prices while engaging in conduct designed to defeat the mechanisms that Congress designed to check such prices and then expect Medicare to pay for the ballooning costs."

"Kickback schemes can undermine our healthcare system, compromise medical decisions, and waste taxpayer dollars," said Phillip Coyne, Special Agent in Charge, Office of the Inspector General of the Department of Health and Human Service's Boston Regional Office. "We will continue to hold pharmaceutical companies accountable for subverting the charitable donation process in order to circumvent safeguards designed to protect the integrity of the Medicare program."

"Today's settlement against Actelion is a victory for the public and underscores the FBI's commitment to safeguarding the financial integrity of the Medicare program," said Harold H. Shaw, Special Agent in Charge of the Federal Bureau of Investigation, Boston Field Division. "Simply put, the goal of the FBI's Health Care Fraud program is to ensure that patients receive the appropriate treatments and therapies according to their medical needs, without corrupt or profit-driven influence of drug manufacturers."

On June 16, 2017, after the conduct alleged in today's settlement agreement, Johnson & Johnson acquired Actelion. Johnson & Johnson was not involved, directly or indirectly, in the alleged conduct and the allegations above do not relate in any way to Johnson & Johnson.

U.S. Attorney Lelling, Assistant Attorney General Hunt, HHS-OIG SAC Coyne, and FBI SAC Shaw made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling's Office, and by Trial Attorneys Augustine Ripa and Sarah Arni of the Justice Department's Civil Division.

Attachment(s):

[Download Actelion_Settlement_Agreement.pdf](#)

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Updated December 6, 2018

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FOR IMMEDIATE RELEASE

Wednesday, December 20, 2017

United Therapeutics Agrees to Pay \$210 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation

BOSTON – The U.S. Attorney's Office announced today that pharmaceutical company United Therapeutics Corporation (UT), a seller of pulmonary arterial hypertension (PAH) drugs, has agreed to pay \$210 million to resolve allegations that it violated the False Claims Act by paying kickbacks to Medicare patients through a purportedly independent charitable foundation.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively "co-pays"). These co-pay obligations may be substantial for expensive medications. Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs.

UT sells a number of PAH drugs, including Adcirca, Remodulin, Tyvaso, and Orenitram. As part of today's settlement, the government alleged that UT used a foundation, which claims 501(c)(3) status for tax purposes, as a conduit to pay the co-pay obligations of thousands of Medicare patients taking its PAH drugs. From February 2010 through January 2014, the government alleged, UT routinely obtained data from the foundation detailing how many patients on each UT PAH drug the foundation had assisted and how much the foundation had spent on those patients. The government alleged that UT used this data to decide the amount to donate to the foundation. At the same time, the government alleged, UT had a policy of not permitting Medicare patients to participate in its free drug program (which was open to other financially needy patients) even if those Medicare patients could not afford their co-pays for UT drugs. Instead, in order to generate revenue from Medicare and to induce purchases of its PAH drugs, UT allegedly referred Medicare patients prescribed its PAH drugs to the foundation, which resulted in claims to Medicare to cover the cost of those drugs.

"UT used a third party to do exactly what it knew it could not lawfully do itself," said Acting United States Attorney William D. Weinreb. "According to the allegations in today's settlement agreement, UT understood

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that the third-party foundation used UT's money to cover the co-pays of patients taking UT drugs. UT's payments to the foundation were not charity for PAH patients generally, but rather were a way to funnel money to patients taking UT drugs. The Anti-Kickback Statute exists to protect Medicare, and the taxpayers who fund it, from schemes like these that leave Medicare holding the bag for the costs of expensive drugs."

"While we support efforts to provide patients with access to needed medications, such assistance must comply with federal law. Today's settlement shows that the government will hold accountable drug companies that attempt to use illegal kickbacks to defeat mechanisms Congress designed to act as a check on drug pricing and healthcare costs," said Principal Deputy Assistant Attorney General Chad A. Readler of the Justice Department's Civil Division.

UT also has entered into a corporate integrity agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The five-year CIA requires, among other things, that UT implement measures designed to ensure that arrangements and interactions with third-party patient assistance programs are compliant with the law. In addition, the CIA requires reviews by an independent review organization, compliance-related certifications from company executives and Board members, and the implementation of a risk assessment and mitigation process.

"Our corporate integrity agreement requires United Therapeutics to implement controls and monitoring designed to promote true independence from any patient assistance programs to which it donates," said Gregory E. Demske, Chief Counsel to the Inspector General for the United States Department of Health and Human Services. "Without true independence, a drug company can use a foundation as a conduit for improper payments that expose the taxpayer-funded Medicare program to the risk of abuse."

Acting U.S. Attorney Weinreb, Acting Assistant Attorney General Readler, and HHS- OIG Chief Counsel Demske made the announcement today. This matter was investigated by HHS-OIG, the Federal Bureau of Investigation, the United States Postal Inspection Service, and the United States Department of Veterans Affairs Office of Inspector General, and was handled by Assistant U.S. Attorneys Gregg Shapiro, Abraham George, and Deana El-Mallawany of Weinreb's Office, and by Trial Attorneys Augustine Ripa and Sarah Arni of the Justice Department's Civil Division.

Attachment(s):

[Download United Therapeutics Settlement Agreement](#)

Topic(s):

Health Care Fraud

Component(s):

[USAO - Massachusetts](#)

Updated December 20, 2017



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Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

Tuesday, January 21, 2020

Fourth Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients

U.S. Attorney's Office has collected more than \$850 million in settlements involving pharmaceutical companies using third-party foundations as instruments for kickbacks

BOSTON – The U.S. Attorney's Office announced today that Patient Services, Inc. ("PSI"), a foundation based in Midlothian, Va., has agreed to pay \$3 million to resolve allegations that it violated the False Claims Act by enabling certain pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.

The government alleged that PSI worked with various pharmaceutical companies to design and operate certain funds that funneled money from the companies to patients taking the specific drugs the companies sold. These schemes enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their drugs. The schemes also minimized the possibility that the companies' money would go to patients who were not taking the companies' drugs.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, "co-pays"). Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs. The law further prohibits third parties, such as co-pay foundations, from conspiring with pharmaceutical companies to violate the Anti-Kickback Statute.

"Pharmaceutical companies cannot use foundations to funnel drug co-payments disguised as routine charitable donations, all to prop up excessive drug prices. PSI allegedly operated as a vehicle for specific pharmaceutical companies essentially to pay kickbacks at the ultimate expense of the American taxpayers who support the Medicare program," said United States Attorney Andrew E. Lelling. "We will continue to pursue this kind of enforcement until the practice disappears."

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"The Department is committed to ensuring that foundations are not used as mere conduits to funnel kickbacks from pharmaceutical companies to Medicare patients and to increase company profits while avoiding an important cost-control aspect of the Medicare program," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "We will continue to combat unlawful kickback arrangements and their pernicious influence on our health care system."

"Few things undermine public confidence quite like finding out the pharmaceutical companies and non-profits they entrust with their health and financial peace of mind have been playing fast and loose with the law. Schemes like these, and the individuals and organizations who perpetrate them, are an affliction on our health care systems," said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. "This settlement demonstrates the FBI's resolve to ensure that patients receive care that is based solely on sound medical judgment, and not compromised by kickbacks."

"Foundations operating patient assistance programs should operate with integrity and act independently from their donors," said Gregory E. Demske, Chief Counsel to the Inspector General. "Our Integrity Agreement is designed to promote such independence and monitor the foundation to reduce the risk of future kickbacks."

The United States alleged that PSI conspired with three pharmaceutical manufacturers – Insys, Aegerion, and Alexion – to enable them to pay kickbacks to Medicare patients taking their drugs. Details of the alleged conduct can be found in attached addendum.

The amount of the settlement announced today was determined based on analysis of PSI's ability to pay after review of its financial condition.

PSI entered a three-year Integrity Agreement (IA) with HHS-OIG as part of the settlement. The IA requires, among other things, that PSI implement measures designed to ensure that it operates independently and that its arrangements and interactions with pharmaceutical manufacturer donors are compliant with the law. In addition, the IA requires compliance-related certifications from PSI's Board of Directors and detailed reviews by an independent review organization.

PSI is the fourth foundation to settle allegations of kickbacks. In total, the four foundations (PSI, The Assistance Fund, Chronic Disease Fund, and Patient Access Network Foundation) have paid \$13 million. In addition, the U.S. Attorney's Office has collected more than \$840 million in total from eight pharmaceutical companies (United Therapeutics, Pfizer, Actelion, Jazz, Lundbeck, Alexion, Astellas and Amgen) to resolve allegations that they used third-party foundations as instruments for kickbacks.

U.S. Attorney Lelling, HHS-OIG Chief Counsel Demske and FBI SAC Bonavolonta made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorney Gregg Shapiro, of Lelling's Affirmative Civil Enforcement Unit, and Trial Attorneys Sarah Arni and Augustine Ripa, of the Department of Justice's Civil Division.

ADDENDUM

PSI's Breakthrough Cancer Pain Fund. In late 2013, PSI and Insys began discussing a potential copayment assistance fund for Subsys, a sublingual form of fentanyl, a powerful opioid painkiller. Subsys was approved for the treatment of breakthrough cancer pain in opioid-tolerant patients. PSI worked with Insys to create a budget for the "Breakthrough Cancer Pain" fund. Insys was the only donor to the fund. PSI provided Insys, through the Insys Reimbursement Center, with access to a "referral portal," where Insys could see the status of each patient that it referred to PSI, including whether that patient had received copay assistance from PSI and the amount of the assistance. PSI did not provide access to the referral portal to other manufacturers of fentanyl products that did not donate to the fund. PSI knew that Insys was referring patients to the Breakthrough Cancer Pain fund who did not have cancer, but PSI stated that it would only prevent "off-label

use...if the Donor wants us to.” PSI provided Insys with monthly “invoices” to cover the patients who had received assistance from PSI. PSI worked to avoid covering patients taking fentanyl products other than Subsyst, noting that PSI “cannot allow them to deplete funds from INSYS.”

PSI’s HoFH Fund. Aegerion sold Juxtapid, which is approved to treat patients with homozygous familial hypercholesterolemia (“HoFH”). In 2013, at Aegerion’s request, PSI created a fund, supported only by Aegerion donations, for HoFH. PSI represented to Aegerion that “it makes more sense to have industry provide a very small amount of funding [in the form of donations for copayment coverage] to gain a reimbursement vehicle rather than give compassionate product.” PSI’s HoFH fund allowed Aegerion to pay for Medicare patients’ copayments to eliminate any price sensitivity to physicians prescribing and patients taking Juxtapid. Aegerion participated in establishing the patient eligibility criteria that PSI used to cover the copayment obligations of patients taking Juxtapid.

PSI’s CMD Fund. Alexion sells Soliris, an intravenously administered complement inhibitor. From Jan. 1, 2010, through June 30, 2016, Soliris was indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (“PNH”) to reduce hemolysis and for the treatment of patients with atypical hemolytic uremic syndrome (“aHUS”) to inhibit complement-mediated thrombotic microangiopathy. Alexion approached PSI in January 2010 to request that PSI create a fund to provide Soliris patients with financial assistance, such as coverage for Medicare copays for Soliris, health insurance premiums, infusion and nursing services, and travel expenses. Over the next several months, Alexion and PSI discussed the coverage parameters that Alexion desired for the fund, including Alexion’s desire that PSI “not support a patient with any of these diagnoses for other reasons tha[n] Soliris therapy.” PSI opened an orphan disease fund entitled Complement Mediated Diseases (“CMD”) to provide assistance to patients taking Soliris. Except in rare instances, PSI provided financial assistance from the CMD fund only if a patient was taking Soliris. PSI provided Alexion with access to PSI’s referral portal software, through which PSI reported information back to Alexion confirming the specific Soliris patients who were approved for copay or other financial assistance from PSI and through which PSI detailed payments to those patients.

Attachment(s):

[Download PSI Settlement Agreement.pdf](#)

Topic(s):

Health Care Fraud

Component(s):

[USAO - Massachusetts](#)

Updated January 22, 2020



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Department of Justice

U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

Wednesday, November 20, 2019

Third Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients

BOSTON – The U.S. Attorney's Office announced today that The Assistance Fund ("TAF"), a foundation based in Orlando, Fla., has agreed to pay \$4 million to resolve allegations that it violated the False Claims Act by enabling certain pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.

TAF operated a fund that was ostensibly for any Medicare patient with multiple sclerosis (MS). The government alleged, however, that TAF conspired with three MS drug manufacturers so that the fund functioned as a conduit for money from those manufacturers to patients taking their MS drugs. The conspiracy enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their MS drugs. The conspiracy also minimized the possibility that the companies' money would go to patients taking competing MS drugs made by other companies.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, "co-pays"). Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs. The law further prohibits third parties, such as co-pay foundations, from conspiring with pharmaceutical companies to violate the Anti-Kickback Statute.

"Pharmaceutical companies and foundations cannot undermine the Medicare program through the use of kickbacks disguised as routine charitable donations. TAF operated as a vehicle for specific pharmaceutical companies to pay kickbacks at the ultimate expense of the American taxpayers who support the Medicare program," said United States Attorney Andrew E. Lelling. "We will continue to pursue this kind of enforcement until the practice disappears."

"TAF cared more about helping its big pharma donors make money than about helping individual patients in need of life changing assistance. The FBI is proud to be a part of the investigation that brought TAF's corrupt

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practices to light, and we will continue to seek justice against any person or entity involved in such schemes,” said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division.

“Foundations that coordinate with pharmaceutical company donors to benefit the donors are not operating independently to equitably benefit needy patients,” said Gregory E. Demske, Chief Counsel to the Inspector General. “Our Integrity Agreements promote independence between foundations and their donors and require the foundations to provide assistance to eligible patients on a first-come, first-served basis.”

The United States alleged that TAF conspired with three MS drug manufacturers – Teva, Biogen, and Novartis – to enable them to pay kickbacks to Medicare patients taking their drugs. Details of the alleged conduct can be found in attached addendum.

The amount of the settlement announced today was determined based on analysis of TAF’s ability to pay after review of its financial condition.

TAF entered a three-year Integrity Agreement (IA) with HHS-OIG as part of the settlement. The IA requires, among other things, that TAF implement measures designed to ensure that it operates independently and that its arrangements and interactions with pharmaceutical manufacturer donors are compliant with the law. In addition, the IA requires compliance-related certifications from TAF’s Board of Directors and detailed reviews by an independent review organization.

TAF is the third foundation to settle allegations of kickbacks. In total, the three foundations (TAF, Chronic Disease Fund, and Patient Access Network Foundation) have paid \$10 million. In addition, the United States has collected more than \$840 million in total from eight pharmaceutical companies (United Therapeutics, Pfizer, Actelion, Jazz, Lundbeck, Alexion, Astellas and Amgen) to resolve allegations that they used third-party foundations as instruments for kickbacks.

U.S. Attorney Lelling, HHS-OIG Chief Counsel Demske and FBI SAC Bonavolonta made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling’s Affirmative Civil Enforcement Unit, with assistance from Trial Attorney Douglas Rosenthal, of the Department of Justice’s Civil Division.

ADDENDUM

TAF’s solicitation and receipt of payments from Teva that correlated with TAF’s spending on Copaxone renewal patients. Teva sells Copaxone, and TAF’s MS fund provided grants to cover Medicare co-pays for patients taking Copaxone. TAF’s MS fund also provided grants to cover Medicare co-pays for patients taking other MS drugs, such as Avonex and Tysabri, which Biogen sells, and Gilenya, which Novartis sells. In the month of December prior to each of the years 2011-2015, TAF conveyed to Teva how much money TAF’s MS fund needed to renew co-pay grants for the fund’s existing Copaxone patients in the upcoming year. In order to determine these amounts, which ranged from over \$18 million to over \$30 million per year, TAF multiplied the number of Copaxone patients in the fund by the fund’s average grant amount, and then added the cost of TAF’s administrative fee. TAF understood that Teva knew how TAF was calculating the amounts of these funding requests, and that, accordingly, Teva was using TAF’s MS fund as a conduit to cover Medicare co-pays for Copaxone patients.

TAF’s practice of not maintaining wait lists and its coordination of the openings of the MS fund with Teva, Biogen, and Novartis. During the period from 2011-2014, TAF’s MS fund frequently ran out of funding and was closed to new patients. If any patients applied for co-pay assistance at that time, TAF did not maintain a wait list of such patients. As a consequence, whenever TAF’s MS fund received a payment and opened to new patients, the fund provided grants to the patients who applied immediately after the opening and did not provide grants to patients who had sought to apply earlier, but at a time when the fund was closed. As described further below, TAF’s practice of not maintaining wait lists enabled TAF to coordinate with Teva,

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Biogen, and Novartis to ensure that TAF used the companies' funding to cover the co-pays of patients taking their respective drugs.

TAF's coordination with Teva. During the period from 2011 to 2014, Teva not only made large payments to TAF's MS fund to cover the renewal of grants for Copaxone patients at the beginning of each year, Teva also made numerous smaller payments, typically less than \$3 million each, to TAF's MS fund at subsequent times during each year. In conjunction with each of these smaller payments, TAF coordinated with Teva and Teva's vendor, Advanced Care Scripts ("ACS"), to ensure that Copaxone patients received a disproportionate share of the grants from the fund during each window when the fund opened after a Teva payment. Each time that Teva was prepared to make a payment, TAF understood that ACS had told Teva how many Copaxone patients were awaiting assistance. Meanwhile, TAF had told Teva the average MS fund grant amount at the time of the payment. TAF knew that Teva was multiplying the average grant amount by the number of waiting Copaxone patients to determine the amounts Teva would pay to TAF's MS fund. TAF further knew that, whenever Teva made a payment to TAF's MS fund and the fund opened, ACS immediately would send a "batch file" of Medicare co-pay assistance applications for Copaxone patients. As a result, each time TAF's MS fund opened after one of Teva's post-January payments during this period, Copaxone patients received a substantial majority of the grants that the fund provided, even though Copaxone accounted for much less than a majority of the overall MS drug market. Further, TAF maintained a "portal" that gave ACS real-time access to the enrollment status of the patients ACS referred; the portal, as TAF knew, enabled ACS to update Teva on the number of Copaxone patients who had received grants from TAF's MS fund.

TAF's coordination with Biogen. Biogen made payments to TAF's MS fund on May 24 and July 17, 2012, as part of a coordinated effort by TAF and Biogen to use Biogen's money to cover Medicare co-pays for Tysabri patients. TAF knew that, when the fund opened after each of these two Biogen payments, ACS immediately would send a "batch file" of Medicare co-pay assistance applications for Tysabri patients. As a result, when TAF's MS fund opened after Biogen's payments on May 24 and July 17, 2012, Tysabri patients received a disproportionate share of the grants that the fund provided. During the course of this scheme, a TAF co-founder e-mailed a Biogen vice president and referred to the scheme as the "TYS[abri] project." The e-mail confirmed that the scheme had succeeded in funneling money from Biogen to Tysabri patients through TAF's MS fund.

TAF's coordination with Novartis. Beginning in October 2012, TAF and Novartis began to coordinate on a means of ensuring that Novartis's next payment to TAF's MS fund would go almost exclusively to Gilenya patients. Ultimately, TAF and Novartis agreed that Novartis would pay TAF's MS fund \$1,418,000 and that TAF would open the fund at 6:00 p.m. on Friday, December 14, 2012. At the time, TAF knew that Novartis had arranged for staff from Novartis's vendor, Express Scripts, to work overtime that night and the following morning to refer Gilenya patients to TAF's MS fund for Medicare co-pay assistance. Express Scripts and TAF referred to this effort as their "12/15 Saturday project." TAF knew that the timing of the opening of the fund, and the readiness of Express Scripts to submit applications on behalf of Gilenya patients at that time, would result in Gilenya patients receiving a disproportionate share of the grants from the fund while it was open. After the fund closed on Saturday, December 15, 2012, TAF confirmed that, during the brief period the fund had been open, TAF used Novartis's money to provide Medicare co-pay grants to 374 Gilenya patients and 6 non-Gilenya patients for 2013.

TAF's discrimination against Tysabri patients in 2014. In late December 2012, Biogen provided TAF's MS fund with funding that TAF understood was to cover grant renewals in 2013 for patients on Biogen's MS drugs, Tysabri and Avonex. During 2013, TAF applied that Biogen funding to grants for patients on those two Biogen drugs. In late 2013, TAF learned that Biogen did not intend to support TAF's MS fund for 2014. At the time, TAF also knew that the Medicare co-pay for Tysabri was significantly higher than the Medicare co-pays for the other MS drugs TAF's MS fund covered. Because Biogen would not support TAF's MS fund in 2014, and because the co-pays for Tysabri were higher than for other MS drugs, TAF decided not to renew co-pay

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assistance grants to a number of Tysabri patients in 2014. This thereby increased the available funding for assistance to patients taking drugs made by companies such as Teva that were continuing to finance TAF's MS fund.

Attachment(s):

[Download TAF_Settlement_Agreement.pdf](#)

Topic(s):

Health Care Fraud

Component(s):

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Updated November 20, 2019



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U.S. Attorney's Office

District of Massachusetts

FOR IMMEDIATE RELEASE

Friday, October 25, 2019

Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients

BOSTON – The U.S. Attorney's Office announced today that two foundations, Chronic Disease Fund, Inc. d/b/a Good Days from CDF ("CDF"), and Patient Access Network Foundation ("PANF"), have agreed to pay \$2 million and \$4 million, respectively, to resolve allegations that they violated the False Claims Act by enabling pharmaceutical companies to pay kickbacks to Medicare patients taking the companies' drugs.

The government alleged that CDF and PANF worked with various pharmaceutical companies to design and operate certain funds that funneled money from the companies to patients taking the specific drugs the companies sold. These schemes enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their drugs. The schemes also minimized the possibility that the companies' money would go to patients taking competing drugs made by other companies.

When a Medicare beneficiary obtains a prescription drug covered by Medicare Part B or Part D, the beneficiary may be required to make a partial payment, which may take the form of a co-payment, co-insurance, or deductible (collectively, "co-pays"). Congress included co-pay requirements in these programs, in part, to encourage market forces to serve as a check on health care costs, including the prices that pharmaceutical manufacturers can demand for their drugs. The Anti-Kickback Statute prohibits pharmaceutical companies from offering or paying, directly or indirectly, any remuneration – which includes money or any other thing of value – to induce Medicare patients to purchase the companies' drugs. The law further prohibits third parties, such as co-pay foundations, from conspiring with pharmaceutical companies to violate the Anti-Kickback Statute.

"According to the allegations in today's settlements, CDF and PANF functioned not as independent charities, but as pass-throughs for specific pharmaceutical companies to pay kickbacks to Medicare patients taking their drugs," said United States Attorney Andrew E. Lelling. "As a result, CDF and PANF enabled their 'donors' (the pharmaceutical companies) to undermine the Medicare program at the expense of American taxpayers."

"OIG continues to be concerned by evidence indicating that foundations are not operating independently from their donors," said Gregory E. Demske, Chief Counsel to the Inspector General. "Our Integrity

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Agreements promote such independence and require legal determinations about whether the foundations' future operations of their assistance programs are compliant with the Anti-Kickback Statute."

"Today's settlements are a warning to all pharmaceutical companies, foundations, and others who try to subvert the charitable donation process for their own financial gain at the expense of American taxpayers. Both the Chronic Disease Fund and the Patient Access Network used their status as charities to shield the illegal activities of pharmaceutical companies seeking to maximize profits," said Joseph R. Bonavolonta, Special Agent in Charge of the FBI Boston Division. "The FBI and our partners will continue to hold organizations accountable, and to protect and preserve the Medicare system, and the taxpayers who fund it, from kickback schemes like these."

The United States alleged that, from 2010 through 2014, CDF conspired with five pharmaceutical companies – Novartis, Dendreon, Astellas, Onyx, and Questcor – to enable them to pay kickbacks to Medicare patients taking their drugs. It is further alleged that, from 2011 through 2014, PANF permitted four pharmaceutical companies – Bayer, Astellas, Dendreon, and Amgen – to use PANF as a conduit to pay kickbacks to Medicare patients taking their drugs. Details of the conduct can be found in attached addendum.

The amounts of the settlements announced today were determined based on analysis of each foundation's ability to pay after review of its financial condition.

CDF and PANF each entered a three-year Integrity Agreement (IA) with OIG as part of their respective settlements. The IAs require, among other things, that the foundations implement measures designed to ensure that they operate independently and that their arrangements and interactions with pharmaceutical manufacturer donors are compliant with the law. In addition, the IAs require compliance-related certifications from the Boards of Directors and detailed reviews by independent review organizations.

U.S. Attorney Lelling, HHS-OIG Chief Counsel Demske and FBI SAC Bonavolonta made the announcement today. The U.S. Postal Inspection Service also assisted with the investigation. The matter was handled by Assistant U.S. Attorneys Gregg Shapiro and Abraham George, of Lelling's Affirmative Civil Enforcement Unit.

ADDENDUM

CDF's PNET Co-pay Fund for Novartis. In May 2011, Afinitor, a Novartis product, was approved to treat progressive neuroendocrine tumors of pancreatic origin ("PNET"). In 2012, Novartis asked CDF to open a co-pay fund to cover Afinitor co-pays for PNET patients. At that time, CDF knew that Sutent, a Pfizer drug, also was approved to treat PNET. In August 2012, at Novartis' request, CDF opened a supposed "PNET" fund. The fund, which Novartis financed alone, covered co-pays only for Afinitor; it did not cover co-pays for Sutent, the other approved PNET drug.

CDF's Provision of Data to Dendreon for the mCRPC Fund. Provenge, a Dendreon product, is an immunotherapy that the FDA approved in April 2010 for treatment of metastatic castration resistant prostate cancer ("mCRPC"). In or about January 2010, Dendreon contacted CDF to request that CDF create a mCRPC fund. At that time, Provenge's principal competitor therapy was Taxotere, a less costly injectable therapy indicated for treatment of various types of cancer. CDF opened its mCRPC fund in June 2010, and, from that time until August 2011, Dendreon alone financed CDF's mCRPC fund. From June 2010 through 2011, at Dendreon's request and on multiple occasions, CDF provided Dendreon with data concerning the number of Provenge patients receiving money from CDF's mCRPC fund, the number of Taxotere patients receiving money from the fund, and the average amounts of money the fund was providing to Provenge and Taxotere patients, respectively. In May 2011, following the FDA approval of Zytiga, an oral therapy indicated for treatment of mCRPC, CDF also provided Dendreon with information concerning the number of Zytiga patients receiving money from CDF's mCRPC fund. CDF's provision of this information made it possible for Dendreon to confirm that CDF was using Dendreon's money primarily to cover co-pays for Provenge, even though other mCRPC drugs were on the market.

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CDF's ARI Co-pay Fund for Astellas. Xtandi, an Astellas product, is indicated for treatment of mCRPC for patients who have failed chemotherapy. After the launch of Xtandi in September 2012, Astellas provided funding for the mCRPC fund at CDF. Xtandi is an androgen receptor inhibitor ("ARI"); none of the other major mCRPC drugs is an ARI. In May 2013, Astellas contacted CDF to request the opening of an ARI fund, which would cover mCRPC patients' co-pays for ARIs, but not for other mCRPC drugs. CDF knew this meant that Astellas was seeking to earmark money for Xtandi patients, and not others, because Xtandi was the dominant ARI drug for treatment of mCRPC. On July 1, 2013, at Astellas' request, CDF opened an ARI fund. Astellas alone financed CDF's ARI fund. As CDF intended, Xtandi patients received nearly all of the money that the fund disbursed.

CDF's Multiple Myeloma Travel Fund for Onyx. In July 2012, Onyx (now owned by Amgen) received approval to market Kyprolis as a third-line treatment for multiple myeloma. Kyprolis must be infused at a health care facility. At around the time of the approval, Onyx asked CDF to create a fund that, ostensibly, would cover health care related travel expenses for patients taking any multiple myeloma drug. At Onyx's request, CDF created the fund, which Onyx alone financed. Internally, CDF at times referred to the fund as the "Kyprolis Travel" fund, and, in fact, it functioned primarily to cover travel expenses for patients taking Kyprolis.

CDF's Provision of Data to Onyx for the Multiple Myeloma Co-Pay Fund. CDF operated a fund that covered co-pays for multiple myeloma drugs, including Kyprolis and several other drugs. CDF's multiple myeloma co-pay fund received financing from several pharmaceutical manufacturers. In 2013, CDF provided Onyx with data detailing the amounts CDF had spent, and anticipated spending, on Kyprolis co-pays. This enabled Onyx to view CDF's funding requests as seeking amounts necessary to pay Kyprolis co-pays but not the co-pays of any other multiple myeloma drug. In 2013, after receiving this information, Onyx paid CDF just enough to cover CDF's anticipated spending on co-pays for Kyprolis patients.

CDF's MS, Lupus, and RA "Exacerbation" Funds for Questcor. In 2010, 2011, and 2012, respectively, Questcor (now owned by Mallinckrodt), the maker of Acthar Gel, approached CDF and requested that CDF open separate funds for "exacerbations" (i.e., flare-ups) of multiple sclerosis, lupus, and rheumatoid arthritis, respectively. CDF opened these "exacerbation" funds, and Questcor alone financed them. By design, the multiple sclerosis "exacerbation" fund did not cover drugs (other than Acthar) that treated multiple sclerosis, the lupus "exacerbation" fund did not cover drugs (other than Acthar) that treated lupus, and the rheumatoid arthritis "exacerbation" fund did not cover drugs (other than Acthar) that treated rheumatoid arthritis. After establishing the funds, CDF provided reports to Questcor that enabled Questcor to determine how much money CDF already had spent on Acthar patients and how much more money CDF would need to cover the Acthar co-pays for patients Questcor referred to CDF.

PANF's Prostate Cancer Subfunds. In March 2010, PANF opened a fund that covered co-pays for patients taking any drug that treated prostate cancer. In September 2012, PANF opened a fund that covered co-pays for patients taking drugs that treated mCRPC. PANF's mCRPC fund covered a number of drugs, including Xofigo (a Bayer drug), Xtandi (an Astellas drug), and Provenge (a Dendreon drug), as well as competing drugs made by other companies. After PANF opened its mCRPC fund, Bayer, Astellas, and Provenge worked with PANF to create smaller funds, with each functioning primarily, if not exclusively, to cover the drug of the single company that financed each fund.

- The RIT subfund for Bayer. Xofigo is an alpha particleemitting radioactive therapeutic agent that the FDA approved to treat mCRPC on May 15, 2013. None of the other major drugs to treat mCRPC is radioactive. Prior to the approval of Xofigo, Bayer approached PANF about creating a fund that would cover only radioactive drugs for mCRPC. On May 16, 2013, one day after the FDA approved Xofigo, PANF opened a fund called Radioisotope Treatment of Metastatic Castrate Resistant Prostate Cancer ("RIT"). Bayer alone financed PANF's RIT fund, and Xofigo patients received nearly all of the money the fund disbursed.

- The ARI subfund for Astellas. After hearing about PANF's RIT fund, Astellas contacted PANF about creating an ARI fund that would cover only ARI drugs for mCRPC. Astellas alone financed PANF's ARI fund, and Xtandi patients received the great majority of the money the fund disbursed.
- The GU subfund for Dendreon. Approximately one month after the opening of PANF's RIT fund, PANF and Dendreon began discussions about PANF creating a fund that would cover copays only for immunotherapy treatments for mCRPC. On August 2, 2013, PANF opened a fund called Immunotherapy for Genitourinary Cancer ("GU"). Dendreon alone financed PANF's GU fund, and Provenge patients received nearly all of the money the fund disbursed.

PANF's SHPT Fund for Amgen. Sensipar, an Amgen product, is approved to treat secondary hyperparathyroidism ("SHPT"). The FDA also has approved other drugs to treat SHPT. In September 2011, Amgen approached PANF about creating an SHPT fund. PANF and Amgen then worked together to determine the fund's coverage parameters so that it would cover only Sensipar. In November 2011, PANF launched a SHPT fund with Amgen alone providing the financing. Until June 2014, Sensipar patients received all of the money PANF's SHPT fund disbursed.

Attachment(s):

[Download CDF Settlement Agreement.pdf](#)

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Topic(s):

Health Care Fraud

Component(s):

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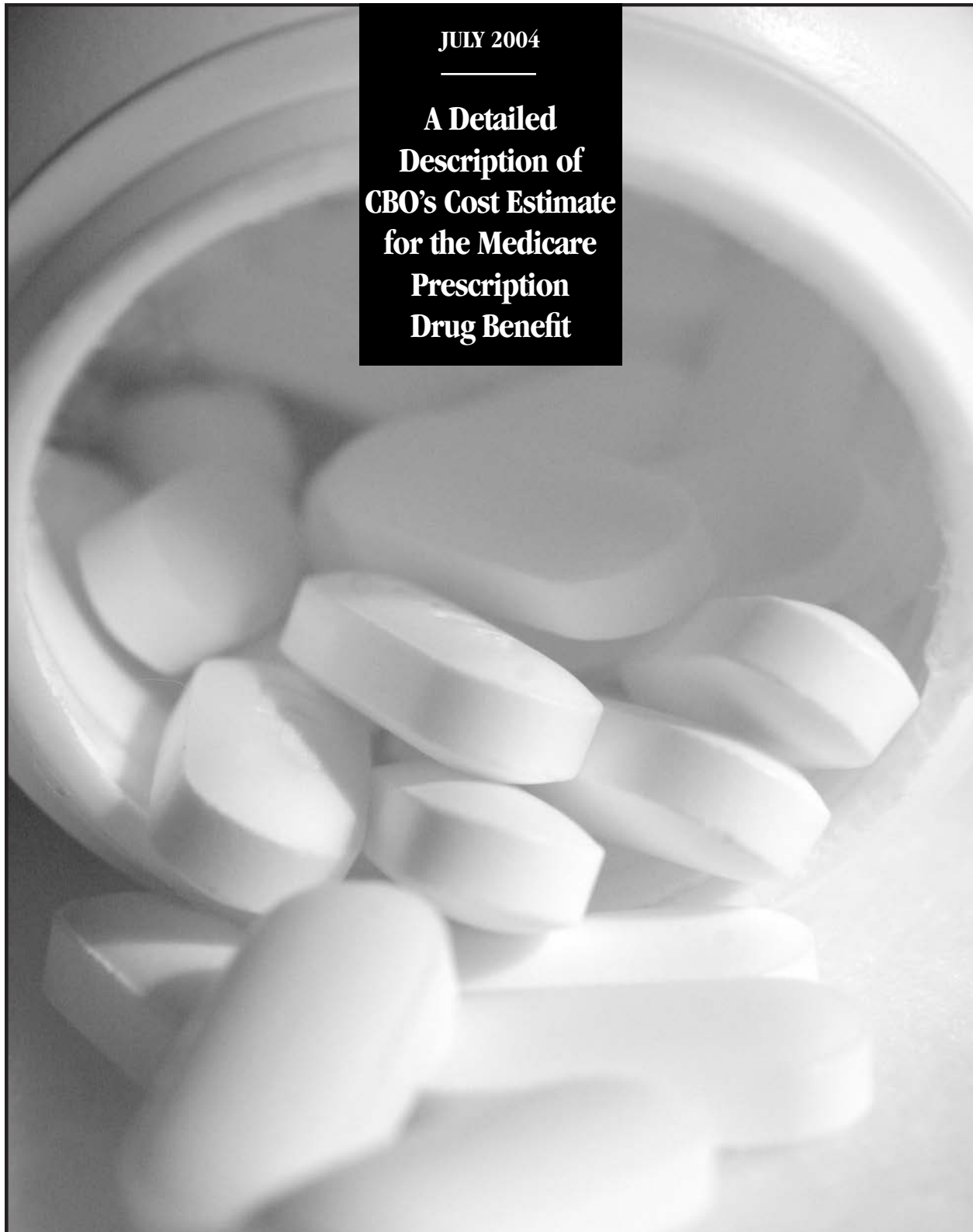
Updated October 25, 2019

CONGRESS OF THE UNITED STATES
CONGRESSIONAL BUDGET OFFICE

A
CBO
PAPER

JULY 2004

**A Detailed
Description of
CBO's Cost Estimate
for the Medicare
Prescription
Drug Benefit**



PFE000562



A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit

July 2004

Note

Numbers in the text and tables of this report may not sum to totals because of rounding.



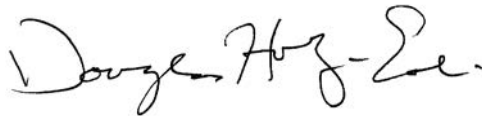
Preface

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 was signed into law by the President on December 8, 2003. The Congressional Budget Office (CBO) provided analysis to the Congress during its deliberations over the addition of an outpatient prescription drug benefit to Medicare and issued in July 2003 federal cost estimates for H.R. 1 and S.1 as passed by the House and Senate as well as an estimate of the conference agreement on H.R. 1 in November 2003.

This paper provides details of the reasoning behind CBO's cost estimate of the prescription drug provisions contained in the Medicare Modernization Act. In accordance with CBO's mandate to provide impartial analysis, this report makes no recommendations. Philip Ellis prepared the report in conjunction with Jeanne De Sa and Eric Rollins, with additional contributions from Niall Brennan, Robert Nguyen, Margaret Nowak, and Shinobu Suzuki. Arlene Holen, Allison Percy, and Tom Bradley, all of CBO, provided thoughtful comments on earlier drafts, as did Len Nichols of the Center for Studying Health System Change and Rachel Schmidt of the Medicare Payment Advisory Commission. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.)

Over the past several years, numerous people at CBO have contributed to the agency's analysis of the issues related to a Medicare drug benefit. Those analysts are Joseph Antos, David Auerbach, James Baumgardner, Shawn Bishop, Kate Bloniarz, Jennifer Bowman, Tom Bradley, Niall Brennan, Hayley Buchbinder, Kathleen Buto, Julia Christensen, Sandra Christensen, Anna Cook, Jeanne De Sa, Philip Ellis, Peter Fontaine, Carol Frost, Samuel Kina, Mara Krause, Steven Lieberman, Deborah Lucas, Mark Miller, Robert Nguyen, Margaret Nowak, Karuna Patel, Eric Rollins, Rachel Schmidt, Emily Shelton, Robert Sunshine, Shinobu Suzuki, Sarah Thomas, Bruce Vavrich, Judith Wagner, and Daniel Wilmoth.

Christine Bogusz edited the paper, and Leah Mazade proofread it. Maureen Costantino prepared the report for publication as well as designed and took the photograph for the cover; Lenny Skutnik printed the copies of the report; and Annette Kalicki produced the electronic versions for CBO's Web site (www.cbo.gov).



Douglas Holtz-Eakin
Director

July 2004

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Summary

The recently enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) contains many provisions that affect the Medicare program specifically and the U.S. health sector more generally. This paper focuses on the provisions that establish a new outpatient prescription drug benefit under Medicare and explains the basis for and rationale behind the Congressional Budget Office's (CBO's) cost estimate of those provisions. CBO estimated that, on net, the Medicare drug benefit would increase mandatory outlays by \$407 billion for fiscal years 2004 to 2013 and would raise federal revenues by \$7 billion over that period. Those estimates consist of many components and reflect the complex interactions of the law's many provisions (see Summary Table 1). In describing how CBO derived its estimates, this paper also presents the agency's analysis of how the drug benefit is anticipated to operate in practice. Taken as a whole, the MMA's other provisions would reduce outlays by \$13 billion and revenues by \$7 billion, in CBO's estimation, for a net savings of \$6 billion. As a result, the MMA would increase deficits—or reduce surpluses—by \$394 billion over the 2004-2013 period (reflecting an increase of \$395 billion in federal outlays and an increase of \$0.5 billion in federal revenues).

Factors in Estimating the Cost of the Basic Medicare Drug Benefit

The MMA established a basic outpatient drug benefit as Part D of Medicare and made it available on a voluntary basis to all Medicare beneficiaries. Estimating the costs of providing that basic benefit involved three main steps: determining the number of beneficiaries who would decide to enroll in a Medicare drug plan; estimating the average and total costs of providing those enrollees with covered benefits; and using the resulting estimate of gross costs to calculate offsetting premium receipts on the basis of the law's subsidy formulas. In addition, CBO had to calculate whether and to what extent employers that cur-

rently provide drug coverage to their retirees on Medicare would continue to do so once the new drug benefit was in place, and whether they would take advantage of an alternative mechanism in the MMA to receive direct payments from Medicare for continuing to provide qualified drug coverage to those retirees.

Participation

Overall, CBO estimated that 87 percent of Medicare beneficiaries would participate in the drug benefit once it became available in 2006, with average enrollment rising from 37 million in that calendar year to 43 million by 2013. In large measure, CBO based those estimates on historical rates of participation in Medicare Part B—which is similar to Part D in that it is a voluntary program, has a premium subsidy of about 75 percent, and imposes significant penalties for late enrollment. Although 94 percent of Medicare beneficiaries enroll in Part B, CBO assumed that participation in Part D would be somewhat lower because many active workers and federal retirees enrolled in Part B would decide not to sign up for the drug benefit. About 19 percent of Medicare beneficiaries would receive subsidized drug coverage through a former employer (and thus would technically not be enrolled in Part D), but the remaining 68 percent would be expected to receive their drug benefits from newly established prescription drug plans or through integrated private health plans that also provided Medicare's other benefits.

Costs for Medicare Drug Plans

Under the MMA, Medicare will not pay directly for drugs provided to its enrollees. Instead, private entities are expected to deliver Part D benefits and will be paid partly on the basis of their expected costs (as expressed in bids) and partly on their actual costs. As a result, CBO's estimate of federal costs took into account what types of entities would participate as drug plans and what sorts of costs they would incur. While those costs would depend

viii A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

Summary Table 1.**CBO's Estimate of the Total Cost of the Medicare Prescription Drug Benefit, Fiscal Years 2004 to 2013**

(Billions of dollars)

	Total Cost of the Benefit
Changes to Direct Federal Spending	
Payments to Medicare drug plans for basic benefits and administrative costs	507
Beneficiaries' premiums	-131
Subsidies for employer and union drug plans	71
Subsidies for low-income benefits	192
Federal Medicaid spending	-142
Transfers from states' Medicaid programs	-88
Other effects on federal spending	-2
Total ^a	407
Changes to Federal Revenues	7
Net Budgetary Impact of the Drug Benefit Provisions	400
Net Budgetary Impact of the MMA's Other Provisions	-6
Net Budgetary Impact of the MMA	394
Memorandum:	
Net Change to Direct Federal Spending	395

Source: Congressional Budget Office.

Note: MMA=Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

- a. Figures for the total impact on direct spending of the drug benefit provisions differ slightly from figures previously released by CBO because certain expenditures have been reclassified from Part D to other provisions of the MMA and vice versa. That difference does not affect CBO's overall cost estimate, however. See Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2005 to 2014* (January 2004), pp. 12-13.

primarily on the share of beneficiaries' drug spending that would be covered by the statutory benefit's design, CBO's estimate assumed that the new benefit would not only redistribute drug spending among the various payers but also change the level of total spending.

The standard drug benefit specified by the MMA for calendar year 2006 will have a \$250 annual deductible; pay 75 percent of covered drug costs between \$250 and \$2,250 (the "initial coverage limit"); provide no further coverage until an enrollee has incurred \$3,600 in out-of-pocket drug costs for the year (the end of the so-called doughnut hole); and pay about 95 percent of covered drug costs beyond that catastrophic threshold. Because the benefit's parameters are indexed to per capita drug

spending, the benefit will cover about the same share of total drug spending for enrollees each year. The catastrophic threshold is defined in terms of the "true out-of-pocket costs" that enrollees actually incur—meaning that enrollees who purchased additional private drug coverage would delay the point at which they reached that threshold and thus would receive less coverage through Medicare, an outcome that CBO assumed would discourage them from purchasing such additional coverage.

To estimate the costs for drug plans of providing those covered benefits, CBO started with a projection of total outpatient drug spending by the Medicare population in the absence of a Medicare drug benefit. The agency then adjusted that total by several factors:

- A “price effect” to reflect the likelihood that average drug prices will be slightly higher because beneficiaries who currently lack drug coverage (about 25 percent of the Medicare population) will become partially insulated from those prices;
- A “use effect” to capture changes in demand for drugs resulting from changes in beneficiaries’ cost-sharing liabilities (to reflect the assumption that beneficiaries’ total drug use will increase somewhat if their own out-of-pocket costs fall);
- An adjustment to reflect the degree to which Medicare drug plans will manage the drug costs of their enrollees (discussed further below); and
- A slight decrease in spending because prices negotiated by Medicare drug plans will be exempt from Medicaid’s best-price provisions—an exemption that gives those plans more leeway to negotiate steeper price discounts from manufacturers since those manufacturers will not have to pass on the same discount to Medicaid.

In estimating the degree of cost management that Medicare drug plans would achieve on average, CBO focused on two main considerations: the incentives that plans would have to control costs (based on the degree of financial risk they would bear and the type of competition they would face); and the tools that they could use to control spending (such as preferred drug lists and pharmacy networks). To summarize the effects of those factors on cost management, CBO estimated the degree to which spending would be reduced in comparison with an unmanaged benefit, such as a traditional indemnity insurance plan. The gross drug savings achieved by the Medicare plans would result from negotiating price discounts or rebates from drug manufacturers and pharmacies; controlling overall drug use; and changing the mix of drugs used. The savings are gross in that they do not reflect the administrative costs of the mechanisms used to achieve them (which were accounted for separately).

Drug plans bearing the full level of financial risk specified by the MMA would achieve average gross drug savings of 20 percent initially, CBO estimated, growing to 25 percent over the budget window. That initial level of savings reflected CBO’s assessment that the MMA would create a

highly competitive environment for drug plans but would somewhat limit the financial risk they faced—in part because of relatively narrow initial “risk corridors”—and also would place certain constraints on their use of cost-management tools. (Under the law’s risk corridor provisions, drug plans incurring costs that exceeded their expected levels by a sufficient degree would be partially compensated by additional federal payments, whereas drug plans with costs that fell far enough below their expectations would have to reimburse Medicare.) Over time, with the gradual widening of the MMA’s risk corridors, drug plans would be exposed to greater financial risk, so CBO’s estimate of gross drug savings rose accordingly. For beneficiaries whose current drug spending already reflected some degree of cost management, however, CBO adjusted that spending to capture only the incremental savings that would be achieved. CBO also assumed that there was some chance that beneficiaries would be enrolled in reduced-risk or “fallback” drug plans as specified by the law; in those cases, CBO estimated that gross savings would be about half as large owing both to the limited financial risk those plans would face and to the less competitive environment in which they would operate.

To calculate the costs of providing covered benefits to Part D enrollees, CBO then applied the law’s drug benefit design and added an estimate of drug plans’ administrative costs (which also reflected the degree of financial risk they would face). In sum, CBO estimated that the average cost per enrollee for providing basic benefits would be \$1,640 in calendar year 2006, rising to \$2,713 in 2013. Multiplying the average costs for each year by the number of enrollees and then converting them to fiscal year outlays, CBO projected total payments to Medicare drug plans of \$507 billion over the 2006-2013 period.

Beneficiaries’ Premiums

A portion of the costs of providing the drug benefit will be financed by premiums paid by or on behalf of beneficiaries, which CBO estimated would total \$131 billion through fiscal year 2013. Although the MMA’s subsidy formulas are complex—specifying both a “direct” subsidy that is fixed and a “reinsurance” subsidy that varies with the share of spending above the catastrophic threshold—CBO estimated average premiums for beneficiaries by applying the law’s 74.5 percent average subsidy to average gross costs. Reflecting the agency’s estimate of average costs per enrollee, average premiums for beneficiaries would rise from \$418 in calendar year 2006 (or about

✕ A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

\$35 per month) to \$692 in 2013 (or about \$58 per month), CBO projected. The premiums that beneficiaries paid would depend on which drug plan they joined, however, and would be higher if they joined a plan with above-average costs overall and lower if they joined a plan with below-average costs. As a result, drug plans will have strong incentives to keep their costs low to attract enrollees, and beneficiaries will be strongly encouraged to consider whether the extra premium of a more costly plan is worth paying—two factors that also affected CBO's assumption about the gross savings that drug plans would achieve on average.

Employers' Subsidies

Former employers are an important source of drug coverage for Medicare beneficiaries, and CBO had projected that in the absence of a Medicare drug benefit, the share of beneficiaries with such coverage would remain roughly constant through 2013. Under the MMA, those employers would have three options for providing drug coverage. First, they could serve as the prescription drug plan for their retirees or could supplement the drug benefits offered by a generally available Medicare drug plan. If employers' supplemental coverage was generous, though, even individuals with very high drug use might never reach the Medicare benefit's catastrophic threshold because they would not incur sufficient out-of-pocket costs themselves. Medicare's average subsidy payments would thus be lower under that option than if employers dropped their drug coverage—that is, stopped providing such coverage themselves to Medicare beneficiaries and did not supplement the drug benefit for Part D enrollees. A third option for employers would be to provide Medicare-eligible retirees with qualified drug coverage and receive a tax-free payment directly from Medicare equal to 28 percent of their total drug costs in a specified dollar range. But CBO estimated that on average, those direct Medicare payments would also be much lower than the net Medicare subsidies for retirees whose employers had dropped drug coverage. At the same time, those direct payments would be accorded favorable tax treatment, making that option somewhat more attractive for employers.

CBO concluded that the net difference in subsidies under the MMA would give employers a new financial incentive to drop prescription drug coverage for Medicare-eligible retirees and that some employers would respond to that incentive. In particular, CBO estimated that 2.7 million Medicare-eligible retirees who would have had more gen-

erous employer drug coverage in 2006 in the absence of a Medicare drug benefit would enroll in Part D but would see their former employer decide not to supplement its basic benefits (although they could have their premium paid or receive some other compensation instead). Of the remaining nonfederal retirees that were projected to have generous employer-sponsored drug coverage, CBO assumed that nearly all—about 8.2 million individuals in calendar year 2006, rising to 9.5 million in 2013—would see their employer take the 28 percent subsidy payment from Medicare, both because of its tax advantages and for reasons of administrative simplicity. CBO's estimate of \$71 billion in direct subsidy payments to qualified employer and union plans for fiscal years 2006 to 2013 reflected the share of drug spending by those retirees that was projected to fall in the covered range. The Medicare drug benefit's provisions would increase revenues by about \$7 billion over that period, CBO further estimated, as businesses reduced expenditures for the (nontaxable) drug benefits they had previously provided and increased them for other (taxable) forms of compensation.

Costs of the Low-Income Drug Subsidies and Effects on Medicaid and Other Direct Spending

Low-Income Drug Subsidies and Transitional Assistance

The MMA established two levels of additional drug benefits for enrollees with relatively low income and countable assets: a substantially higher subsidy for beneficiaries who are either dually eligible for full Medicare and Medicaid benefits or have income below 135 percent of the federal poverty level and few assets; and a somewhat higher subsidy for those with income below 150 percent of the poverty level and assets below a slightly higher limit. Those subsidies would pay all or a portion of those beneficiaries' Part D premiums and substantially reduce their cost-sharing liabilities (both by lowering their copayment rate and by extending that coverage to costs falling between the initial benefit limit and the catastrophic threshold). About 35 percent of beneficiaries enrolled in Part B of Medicare would be eligible for those low-income subsidy benefits, CBO estimated.

In estimating enrollment in the low-income drug subsidy program, CBO assumed that all dual eligibles would re-

ceive the subsidies but that a significant proportion of the remaining eligible population would not apply. That assumption primarily reflected the fact that participation is low in similar Medicaid programs that pay for premiums and cost sharing under Parts A and B of Medicare. (Those programs are for qualified Medicare beneficiaries [QMBs] and specified low-income Medicare beneficiaries [SLMBs], who have income below 120 percent of the poverty level and limited assets.) Ultimately, CBO assumed that almost 70 percent of eligible enrollees would receive low-income subsidies under the MMA. About 75 percent of those eligible for the substantially higher subsidy (including all dual eligibles) would receive it, while about 35 percent of those eligible for the somewhat higher subsidy would receive that benefit. Take-up rates would be slightly lower in the initial years of the benefit.

In estimating the costs of the low-income subsidy payments, CBO assumed that participants would generally have higher average drug costs than beneficiaries who were eligible for those subsidies but chose not to enroll. The total cost of \$192 billion that CBO estimated for the low-income subsidies over 10 years also includes about \$1 billion for the costs of covering the enrollment fees and providing up to \$600 of assistance for certain low-income beneficiaries in conjunction with the Medicare drug discount card. For that transitional assistance program, which is scheduled to operate from mid-2004 through December 2005, CBO assumed a relatively low take-up rate (nearly 1 million enrollees in 2005) because of the program's limited benefits and temporary nature.

Interactions with Medicaid

The MMA transfers responsibility for the prescription drug benefits of dual eligibles from Medicaid to Medicare. As a result, CBO estimated that federal spending on Medicaid would be reduced by \$152 billion through fiscal year 2013 compared with projections of spending in the absence of a Medicare drug benefit. Those savings on drug costs would be partly offset by an additional \$10 billion in federal Medicaid outlays over that period stemming primarily from additional spending on other benefits for Medicare beneficiaries who would enroll in Medicaid or the QMB and SLMB programs as a result of applying for the low-income drug subsidy program. In the absence of other provisions, those federal Medicaid

savings on drug costs would be accompanied by corresponding savings for the states. The MMA's "clawback" provision, however, would recapture a substantial portion of the states' estimated drug savings, which CBO projected would further reduce federal costs by \$88 billion for fiscal years 2004 to 2013.

Other Effects on Direct Spending

CBO estimated that some federal retirees would enroll in a Medicare drug plan; as a result, a portion of their prescription drug costs would be indirectly shifted to Medicare (the figures provided above reflect that estimate). On the basis of that impact, as well as small effects on other federal programs that pay for prescription drugs, CBO estimated that the Medicare law's drug benefit provisions would reduce mandatory federal spending by about \$3 billion through fiscal year 2013. At the same time, the MMA provided \$1.5 billion in mandatory spending for the federal administrative costs of implementing the drug benefit in 2004 and 2005, so the estimated impact on other direct spending was a net reduction of about \$2 billion over 10 years. CBO assumed that the drug benefit would not generally increase or decrease spending for hospitalizations, doctors' visits, or other services paid for under Parts A and B of Medicare and that it would not substantially affect net enrollment in private health plans (Part C).

Uncertainty and Conclusions

Anytime a complex and substantially new program is created, difficulties arise in predicting its outcome, particularly in the case of an entitlement program with a large number of potential enrollees. For many reasons, actual program costs could turn out to be higher or lower than CBO has estimated. Several key variables—including the number of participants in the basic drug benefit or in the low-income subsidy program, their level of drug spending in the absence of a Medicare drug benefit, and the adjustments made to that spending to determine average costs per participant—could deviate, in either direction, from CBO's projections. Until such information becomes available, however, the cost estimate described here represents the agency's best judgment about the net budgetary impact of the Medicare drug benefit that was established by the MMA.

A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit

Introduction

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Public Law 108-173, was passed by the House of Representatives on November 22 and by the Senate on November 25 and was signed into law by the President on December 8, 2003. That legislation contains numerous provisions that modify Medicare's payments to hospitals, doctors, and other health care providers, as well as provisions that affect other parts of the health sector (such as those establishing health savings accounts or changing the rules that govern the introduction of generic prescription drugs). This paper focuses on the provisions of the MMA that create an outpatient prescription drug benefit under Medicare, explaining how the Congressional Budget Office (CBO) generated its cost estimate for those provisions.¹

The provisions of the MMA that established the Medicare drug benefit would increase outlays for direct federal spending by \$407 billion for fiscal years 2004 to 2013, in CBO's estimation.² That projection has several components (see Table 1). Under the law, drug benefits would

be delivered by private-sector entities bearing some financial risk—generally through newly established prescription drug plans (PDPs) or through integrated private health plans that also provide Medicare's other benefits to their enrollees. Those plans would incur costs of \$507 billion in providing the basic statutory drug benefit, CBO projected, which would be partially offset by \$131 billion in premium payments made by or on behalf of enrollees. The law provides a separate payment system for beneficiaries who instead receive qualified drug coverage through plans offered by employers or unions; CBO estimated that Medicare payments to those plans would amount to \$71 billion. The impact of the drug benefit provisions on employers' costs would indirectly raise federal revenues by \$7 billion over the fiscal year 2004-2013 period, in CBO's estimation, modestly offsetting the impact of the increases in direct spending on future federal deficits or surpluses.

In addition to offering a basic drug benefit to all Medicare beneficiaries, the MMA would subsidize more generous drug coverage for certain low-income enrollees, which CBO estimated would cost \$192 billion through fiscal year 2013. Because the new benefit and low-income subsidies would replace the drug coverage that many Medicare beneficiaries receive through Medicaid, federal spending on drugs under Medicaid would decline by \$152 billion compared with projected spending in the absence of a Medicare drug benefit. Those savings would be partly offset by an additional \$10 billion in federal outlays for Medicaid resulting from the new law's drug benefit provisions—largely owing to additional spending on other benefits for Medicare beneficiaries who enroll in Medicaid when they apply for the low-income drug subsidy program. Thus, the net federal Medicaid savings shown in Table 1 were estimated at \$142 billion over 10

1. A section-by-section breakdown of CBO's scoring for the entire MMA was provided in Congressional Budget Office, *H.R. 1, Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (November 2003), and additional details were provided in Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2005 to 2014* (January 2004), pp. 12-13. CBO's scoring of the MMA was also discussed by CBO Director Douglas Holtz-Eakin in his statement, *Estimating the Cost of the Medicare Modernization Act*, before the House Committee on Ways and Means, March 24, 2004.
2. That figure differs slightly from the \$409 billion total shown in recent CBO publications. The reason for the difference is a slight reclassification of certain expenditures from the drug benefit to other provisions of the MMA and vice versa, but the difference does not affect CBO's overall cost estimate for the MMA.

2 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table 1.****CBO's Cost Estimate for the Medicare Prescription Drug Benefit,
Fiscal Years 2004 to 2013**

(Billions of dollars)

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total, 2004- 2008	Total, 2004- 2013
Changes to Direct Federal Spending												
Payments to Medicare Drug Plans for Basic Benefits and Administrative Costs	0	0	33.3	49.9	55.9	60.5	66.3	72.1	80.1	89.3	139.0	507.2
Beneficiaries' Premiums	0	0	-9.1	-12.8	-14.3	-15.5	-17.0	-18.5	-20.6	-22.9	-36.2	-130.6
Subsidies for Employer and Union Drug Plans	0	0	4.7	6.8	7.5	8.3	9.3	10.3	11.5	12.6	19.0	71.1
Subtotal, Basic Drug Benefit	0	0	28.9	43.9	49.1	53.3	58.6	64.0	71.0	79.0	121.8	447.7
Subsidies for Low-Income Benefits	0.1	0.5	8.9	18.1	20.8	23.2	25.7	28.2	31.2	34.8	48.4	191.5
Federal Medicaid Spending	0	0	-6.5	-13.9	-15.3	-17.0	-18.9	-21.0	-23.3	-25.9	-35.6	-141.8
Transfers from States' Medicaid Programs	0	0	-5.7	-9.1	-10.0	-10.8	-11.7	-12.6	-13.7	-14.9	-24.8	-88.5
Other Effects on Federal Spending ^a	0.5	1.0	-0.1	-0.3	-0.3	-0.4	-0.4	-0.5	-0.5	-0.6	0.8	-1.5
Total ^b	0.6	1.5	25.5	38.7	44.3	48.3	53.3	58.1	64.7	72.5	110.7	407.5
Changes to Federal Revenues												
Indirect Effects of Drug Benefit Provisions ^c	0	0	0.4	0.7	0.8	0.8	0.9	1.0	1.2	1.3	1.9	7.2
Net Budgetary Impact												
Medicare Drug Benefit Provisions	0.6	1.5	25.0	38.0	43.5	47.5	52.3	57.1	63.5	71.1	108.8	400.3
Other MMA Provisions	3.4	4.9	2.6	2.1	0.4	-1.1	-2.7	-4.3	-5.2	-6.0	13.3	-6.0
Medicare Modernization Act	4.0	6.5	27.6	40.2	43.9	46.4	49.6	52.8	58.4	65.1	122.1	394.3
Memorandum:												
Net Change to Direct Federal Spending	3.8	6.0	27.5	40.2	44.0	46.5	49.8	53.0	58.7	65.5	121.4	394.8

Source: Congressional Budget Office.

Notes: MMA = Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

- Includes \$1.5 billion in mandatory spending for federal administrative costs of implementing the drug benefit.
- Figures for the total impact on direct spending of the drug benefit provisions differ slightly from figures previously released by CBO because certain expenditures have been reclassified from Part D to other provisions of the MMA and vice versa. That difference does not affect CBO's overall cost estimate, however. See Congressional Budget Office, *The Budget and Economic Outlook: Fiscal Years 2005 to 2014* (January 2004), pp. 12-13.
- Includes the estimated effect on revenues of MMA provisions that would modify the Hatch-Waxman Act (an increase of \$0.2 billion over the 2004-2013 period).

years.³ Another provision of the act would capture a substantial portion of states' savings on Medicaid drug expenditures, reducing federal costs by an estimated \$88 billion. Finally, the Medicare drug benefit would on net reduce mandatory spending for the Federal Employees Health Benefits (FEHB) program and other federal programs that currently pay for prescription drugs, although the MMA also included mandatory spending for the federal administrative costs of implementing the drug benefit. Over 10 years, the net reduction in other direct spending would be about \$2 billion.

Taking into account all of the MMA's provisions, including those unrelated to the drug benefit, CBO estimated that the law would yield a net increase in deficits or a reduction in surpluses of \$394 billion over the fiscal year 2004-2013 period.⁴

This paper aims to explain what each component of CBO's cost estimate for the Medicare drug benefit represents and how those components were derived. In doing so, the paper also reviews how the agency addressed a number of difficult but fundamental questions raised by the prospect of such a new benefit. For example, would Medicare beneficiaries sign up for it—and in particular, would enrollment in the benefit be broad and representative, or would it be concentrated among the small share of beneficiaries with the highest drug costs? Would private-sector entities step forward to provide a stand-alone drug benefit to the Medicare population and accept the degree of financial risk specified by the MMA? If so, how well would they be able to control drug spending, what costs would they incur in doing so, and how would enrollees balance the costs and benefits of competing drug

plans when deciding which one to select? If private-sector entities did not come forward, what would be the costs of providing benefits through reduced-risk or “fall-back” drug plans, and how would the market for drug coverage evolve over time? How would the organizations currently providing drug coverage to many Medicare beneficiaries—such as their former employers—react to the new benefit's provisions? And how would beneficiaries who were eligible for the low-income subsidies respond to their availability?⁵

The first section of this paper focuses on the drug benefit that will be made generally available to Medicare beneficiaries and discusses the factors affecting the number of participants in that program and the costs per participant, both in gross terms and net of beneficiaries' premium payments. It includes a discussion of the related impact on employer-sponsored drug coverage for Medicare beneficiaries and of the payments Medicare will make to qualified employer and union plans for drug costs. The second section focuses primarily on the subsidies for providing more generous drug coverage to certain low-income beneficiaries—and the related provisions affecting federal Medicaid spending—but also covers several other effects on federal outlays. A concluding section notes the uncertainty inherent in estimating the costs of such an entitlement program, given that the federal government will be offering an entirely new type of benefit to a large number of individuals.

Factors in Estimating the Cost of the Basic Medicare Drug Benefit

Eligibility and Enrollment

A key determinant of total federal costs for providing a Medicare drug benefit is the number of beneficiaries who enroll. Under the MMA, benefits will be first available on January 1, 2006, and beneficiaries who are enrolled in either Part A or Part B of Medicare at that time (including those who get their Medicare benefits through a private health plan under Part C) will be eligible for the new prescription drug benefit, which will be established as Part D

3. In a comparable table that CBO released in November 2003, the additional federal Medicaid outlays were included with “other direct spending,” whereas Medicaid drug savings were added to the net savings on drug costs for other federal programs (yielding a 10-year total of \$155 billion). See Congressional Budget Office, *Letter to the Honorable Don Nickles providing additional information about CBO's cost estimate for the conference agreement on H.R. 1* (November 2003).

4. Taken together, the MMA's other provisions would reduce outlays by \$13 billion, CBO estimated, so that the net increase in mandatory outlays for the MMA as a whole would round to \$395 billion. The MMA's other provisions would also reduce revenues—by \$7 billion, CBO projected—nearly offsetting the effect on revenues of the drug benefit provisions.

5. For additional background information and a discussion of how CBO approached many of those questions, see Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare* (October 2002).

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of Medicare.⁶ Enrollment in Part D will be voluntary, however, so CBO modeled the decision to participate as a function of the “carrots and sticks” that potential enrollees would face—carrots in the form of federal subsidies to keep their premiums down and sticks in the form of late-enrollment penalties. In large measure, CBO based its approach for estimating participation in Part D on the experience of Part B, which is also voluntary, has similar premium subsidies and late-enrollment penalties, and enrolls nearly all beneficiaries who are eligible.

Key Considerations. The federal subsidies that will be provided under Part D are a major incentive to enroll in the drug benefit. As discussed in more detail below, those subsidies mean that beneficiaries’ premiums will, on average, cover about 25 percent of the costs of providing the standard Part D benefit. Because of those subsidies, most Medicare beneficiaries by enrolling will receive more in benefits than they will pay in premiums. Even those enrollees who end up paying more in premiums than they save on their drug costs in a given year will derive the benefit of having had insurance protection against the risk of incurring higher out-of-pocket costs. Although beneficiaries generally will not be enrolled in Part D by default—unlike Part B—CBO assumed that the premium subsidy would be sufficient to overcome the hurdle of actively signing up.⁷ Eligible beneficiaries who currently have drug coverage will have a clear incentive to enroll in Part D—or the sponsors of their coverage will want them to enroll—in order to obtain those new federal subsidies, regardless of their current drug use. (CBO estimated that about 75 percent of Medicare beneficiaries have some form of drug coverage, though in many cases that coverage is rather limited.) For beneficiaries who have sufficiently low income and assets, the additional premium and cost-sharing subsidies they are offered will

provide a further inducement to enroll in the basic drug benefit.

Although enrollment in Part D is voluntary, beneficiaries who do not sign up when they are first eligible, and those who disenroll and subsequently reenroll, will be subject to a late-enrollment penalty (unless they maintain drug coverage from certain other sources in the meantime that is at least as generous as the Medicare benefit). For example, beneficiaries who went without drug coverage for two years before signing up would generally pay a surcharge of at least 24 percent of the average premium each year thereafter; as a result, they would very likely owe more in total premium payments over their lifetime than if they had signed up for the Medicare benefit when it was first available.⁸ Even beneficiaries whose current drug use is relatively low will thus have strong financial incentives to enroll in Part D promptly to protect against the risk of having higher drug costs in the future. In essence, the late-enrollment penalty changes the decision about whether to enroll from one that compares next year’s premium with next year’s expected benefits—a choice that could lead beneficiaries to delay signing up until they had recurring, high drug costs—to one that compares lifetime premiums with expected benefits over the same period—a choice that is likely to favor prompt enrollment because of the substantial premium subsidies and the probability of incurring significant drug costs sooner or later.

Estimated Participation. In light of those factors, CBO started with the assumption that the share of eligible Medicare beneficiaries who will participate in Part D will be no larger than the share who enroll in Part B—about 94 percent. In other words, CBO assumed that because 6 percent of all Medicare beneficiaries choose not to participate in Part B—with its 75 percent premium subsidy and substantial late-enrollment penalty—a comparable share of beneficiaries would forgo a drug benefit with a

6. For calendar year 2006, CBO projects that the average number of beneficiaries enrolled in Medicare at any point will be 42.6 million. While most of them will be enrolled in both Part A (Hospital Insurance) and Part B (Supplementary Medical Insurance), CBO projects that 2.7 million will be enrolled only in Part A and 0.5 million will be enrolled only in Part B. The corresponding projections for 2013 are 49.6 million total beneficiaries, with nearly 3.1 million in Part A only and about 0.6 million in Part B only. The number of Part B enrollees (whether enrolled in Part A or not) will thus increase from 39.9 million in 2006 to 46.6 million in 2013.

7. Medicare beneficiaries who also receive full Medicaid benefits (commonly known as dual eligibles) will be enrolled in Part D by default.

8. Under the MMA, the late-enrollment penalty will be the greater of “an amount that the Secretary [of the Department of Health and Human Services, or HHS] determines is actuarially sound” or 1 percent of the national average premium for each “uncovered month.” (See section 1860D–13(b)(3) of the Social Security Act, as amended.) In setting an actuarially sound penalty, HHS would have to take into account the expected program costs for individuals who chose to enroll late even in the face of the penalty, costs that would probably exceed average program costs for other enrollees. That penalty could therefore be greater than the 1-percent-per-month minimum.

similar structure. CBO then reduced the projected rate of participation in Part D below the rate for Part B, for two reasons. First, CBO assumed that Part B enrollees who are active workers and have drug coverage through their employer would keep that primary coverage rather than sign up for the Medicare benefit. Second, CBO assumed that Part B enrollees who are retired but also qualify for the FEHB program or the military's TRICARE For Life (TFL) program would be less likely to participate in a new Medicare drug benefit. Because they already have fairly generous drug coverage, many of them would find that the premium for Part D was not worth the additional benefits. Those active workers and federal retirees together account for about 7 percent of Part B enrollees.⁹

In sum, CBO assumed that 87 percent of all Medicare beneficiaries would elect to participate in the prescription drug benefit. Thus, the average number of Part D participants would rise from 37.2 million in calendar year 2006 to 43.4 million in calendar year 2013, CBO estimated. CBO further assumed that Part D participants would not have systematically higher drug costs than nonparticipants because the combination of premium subsidies and late-enrollment penalties would be sufficient to avoid the insurance-market phenomenon known as adverse selection, in which people who expect to have above-average costs disproportionately enroll.¹⁰ Those participation figures also include a substantial number of beneficiaries—about 19 percent of all Medicare enrollees—who will continue to receive drug coverage through a plan from their former employer or union (which would be subsidized by Medicare through a separate mechanism but

technically would not constitute enrollment in Part D). The reasons that CBO assumed that certain beneficiaries would receive coverage from those sources are discussed separately below. First, however, this paper examines the gross costs and premium payments that would be incurred by the remaining majority of Part D participants and the delivery system through which they would receive their drug benefits.

Gross Costs of Providing the Basic Drug Benefit

Having concluded that enrollment in the Medicare drug benefit would be broadly representative, CBO estimated average and total costs for enrollees in a series of steps. CBO projected what drug spending would be in the absence of a Medicare drug benefit (that is, under prior law); adjusted individual spending levels to reflect provisions of the MMA that would either increase or decrease total drug spending; and then applied the MMA's benefit design provisions to determine the gross costs of providing covered benefits. This section explains what each of those steps involved and specifically reviews the following factors:

- CBO's baseline projections of drug spending under prior law;
- The design of the MMA's standard drug benefit and the provisions for varying, supplementing, and indexing that benefit design over time;
- The delivery mechanisms specified by the law;
- CBO's estimate of the impact that different delivery mechanisms would have on covered drug spending;
- Other provisions of the MMA that CBO judged would affect drug prices or utilization; and
- CBO's estimate of various administrative costs that would be incurred in providing the new drug benefit.

Baseline Drug Spending. Data on current drug spending are not available for all Medicare beneficiaries. CBO therefore chose to develop a microsimulation model for use in generating cost estimates that was designed to capture how a given proposal would affect a representative sample of those beneficiaries. The model contains detailed information about beneficiaries' spending for prescription drugs and Medicare-covered services, their sup-

9. To some extent, those are simplifying assumptions. Some active workers might enroll in a Medicare drug benefit, but under Medicare's secondary-payer rules, their employer's plan would pay first and thus would probably offset most of Medicare's costs. And if more FEHB annuitants or TFL beneficiaries enrolled in Part D than CBO assumed, Medicare spending would be greater, but there would be offsetting federal savings for those programs. In both cases, CBO also assumed that those beneficiaries would be exempt from any late-enrollment penalties if they later lost their drug coverage since that coverage would be at least equivalent to and probably better than the Medicare benefit. As a result, they would not have a strong incentive to enroll in Part D. It is also worth noting that some of the Medicare beneficiaries who do not enroll in Part B are active workers or federal retirees.

10. For a more detailed discussion of issues related to adverse selection and their potential impact on a Medicare drug benefit, see Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare*, pp. 17-23.

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plemental insurance coverage (both public and private), their health status, and their income. The information used in the model is based on data from Medicare claims for 1999 and from the 1999 and 2000 Medicare Current Beneficiary Survey (MCBS), projected forward using CBO's March 2003 economic and technical assumptions and baseline projections of Medicare spending. For drug spending, the MCBS data were adjusted to account for underreporting in survey responses and for missing data on nursing home residents. The assumptions used about subsequent growth rates for per capita drug spending were based on the most recent historical estimates and on projections for national health expenditures made by the Centers for Medicare and Medicaid Services (CMS).¹¹

On the basis of that model, CBO projected the total outpatient drug costs that would be incurred by or on behalf of Medicare beneficiaries in the absence of a new Medicare benefit.¹² For calendar years 2004 to 2013, CBO estimated that cumulative spending would total \$1.84 trillion. Reflecting the assumption that a two-year implementation period would be required before drug benefits could be delivered, however, the focus of CBO's analysis was on spending from 2006 to 2013, which was projected to total \$1.61 trillion. CBO then excluded drug spending covered by Veterans Health Administration (VHA) programs and spending by projected nonparticipants in Part D to generate a total baseline of \$1.36 trillion for drug spending that could be covered by the Medicare benefit.¹³ Under that baseline, average spending for participants would rise from \$3,096 in 2006 to \$5,617 in 2013, while median spending would increase from \$1,913 to \$3,475. (Those figures include spending by participants who are projected to receive coverage through a qualified employer or union drug plan.)

The primary factor that determines the gross federal costs of a drug benefit proposal is the share of enrollees' current drug spending—how much of that \$1.36 trillion—that the new benefit will cover, which is a function of the benefit's design. But CBO's estimates also assume that, rather than simply rearrange who pays for drug spending, the new benefit will change the level of total spending in various ways. Some enrollees will fill more prescriptions or use more brand-name drugs once they gain better insurance coverage, thus increasing overall drug spending. The new Medicare benefit will also give manufacturers somewhat greater leeway to raise prices on certain drugs (to the extent that enrollees become less sensitive to the underlying price of their prescriptions). Conversely, spending will be reduced to the extent that the entities administering the drug benefit make aggressive use of cost-management tools, which can result in substantial price discounts and changes in the mix of drugs prescribed or purchased. Because the provisions of the MMA that affect the drug benefit's cost per enrollee are complicated, CBO's modeling of those provisions was correspondingly complex.

Benefit Design. In addition to specifying a standard benefit design for 2006, the MMA included various rules regarding ways in which the benefit design could be varied or supplemented and defined a mechanism for indexing the benefit's parameters for future years. (It also included provisions that stipulated how the benefit should be provided, such as requirements for determining which drugs would be covered and which pharmacies could be used to fill prescriptions. A discussion of those provisions is presented later in this paper.) The standard drug benefit for calendar year 2006 will have these specifications:

- A \$250 annual deductible;
- Coverage for 75 percent of drug costs (on average) between the deductible and an initial coverage limit of \$2,250;

11. CMS projected that per capita drug spending would increase by 98.6 percent between 2000 and 2006 (an average annual growth rate of 12.1 percent) and by 67.5 percent between 2006 and 2012 (an average annual growth rate of 9.0 percent). See "National Health Care Expenditure Projections: 2002-2012," available at the CMS Web site (www.cms.hhs.gov/statistics/nhe/projections-2002/proj2002.pdf).

12. The calculation excluded spending for drugs already covered by Medicare, such as drugs used during an inpatient hospital admission, which are covered under Part A, and the limited number of drugs used on an outpatient basis that are already covered under Part B.

13. Because the drug benefits provided by the VHA are relatively generous, CBO assumed that Medicare beneficiaries who had been filling prescriptions through that system would continue to do so. For purposes of estimating the effect of the Part D provisions on mandatory federal spending, CBO thus assumed that prescription drug spending by the VHA (which is discretionary) would not be shifted to Medicare—and thus would not differ substantially from the levels projected under prior law.

- A “doughnut hole” beyond \$2,250 in which no coverage is provided until an individual has incurred \$3,600 in out-of-pocket drug costs for the year; and
- Catastrophic coverage of about 95 percent of covered drug costs beyond that point.¹⁴

Subject to the approval of the Department of Health and Human Services (HHS), drug coverage can be offered that deviates from the standard design as long as four key conditions are met: the catastrophic coverage is the same as the standard benefit's; the deductible is no higher than the standard benefit's; the average value of the alternative coverage (based on the drug use of a representative sample of seniors) is the same as the standard benefit's value; and payments by the plan for benefits at the initial coverage limit equal what the plan would have paid using the standard benefit design. Basic drug plans could thus be offered that had a lower deductible combined with slightly higher average coinsurance below the initial coverage limit, or that simply varied the coinsurance rate between the standard benefit's deductible and initial coverage limit (so long as cost sharing in that range averaged 25 percent).¹⁵ Because the cost of providing an alternative benefit design is supposed to be the same as the cost of providing the standard benefit (taking into account the effects of that design on drug use), CBO estimated the MMA's costs as though the standard benefit were offered uniformly.

14. For 2006, cost sharing above the catastrophic threshold will be the greater of 5 percent coinsurance or a copayment of \$2 for all generic drugs and preferred brand-name drugs with generic competitors or \$5 for other drugs including all brand-name drugs without generic competitors. After 2006, the \$2 and \$5 amounts will be indexed to per capita drug costs for the Medicare population.

15. Coverage provided above the initial coverage limit (that is, in the doughnut hole) would not count toward meeting the fourth condition and thus would be treated as an extra benefit. According to the MMA, therefore, a drug plan could not offer a basic benefit with a higher initial coverage limit that was offset by a higher average coinsurance rate above the deductible, even if the overall expected value of that benefit design for a representative sample of seniors was equal to the standard benefit's value. Although HHS could waive those restrictions in a budget-neutral way (that is, without increasing net federal spending), a drug plan might be reluctant to seek such a waiver since providing coverage in the doughnut hole would be most attractive to enrollees with high drug costs and thus could raise the issue of adverse selection for that plan.

The fact that the catastrophic threshold was defined in terms of out-of-pocket costs rather than total drug spending would have been immaterial but for another feature of the MMA—one commonly referred to as the “true out-of-pocket” provision. Under that provision, out-of-pocket costs will generally count toward the catastrophic threshold only if they are incurred by an individual and are not reimbursed by third-party insurance coverage (such as supplemental drug coverage provided by a former employer). As a result, an enrollee with no supplemental drug coverage will reach the catastrophic threshold in 2006 when he or she had purchased \$5,100 worth of covered drugs.¹⁶ Beneficiaries with supplemental coverage, however, would not reach the catastrophic threshold until they had incurred higher levels of total drug spending—and if their supplemental plan included a lower limit on out-of-pocket costs, they would never reach the Medicare benefit's catastrophic threshold. At the same time, costs covered by Medicare's low-income subsidies or by state pharmaceutical assistance programs would still be counted as true out-of-pocket expenses; that is, they would be treated as though the beneficiary had paid them. Beneficiaries with those forms of supplemental coverage could therefore reach the catastrophic threshold once they had purchased \$5,100 worth of drugs in 2006 (and thus, as an accounting matter, most of their remaining drug spending would be covered by the standard Medicare benefit and not by those low-income subsidies).

Drug plans could also provide coverage that was more generous than the standard design, but the costs of any extra benefits would not be federally subsidized, so beneficiaries would have to pay an additional premium for those benefits. Such supplemental coverage would also delay the point at which the catastrophic threshold was reached and thus could reduce the cost of providing the standard drug benefit. Yet beneficiaries with very high drug spending would find it disadvantageous to purchase such coverage because in addition to paying their supplemental premium, they would still need to incur \$3,600 in out-of-pocket costs in 2006 before they reached the

16. At that point, the beneficiary would have paid the \$250 deductible; \$500 in cost sharing to cover 25 percent of his or her drug costs between that deductible and the \$2,250 initial coverage limit; and \$2,850 in spending above that limit (which would be paid for entirely by the beneficiary), for a total of \$3,600 in out-of-pocket costs.

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catastrophic threshold.¹⁷ Consequently, CBO assumed that individuals would not purchase supplemental coverage in a way that substantially affected the cost of providing the standard drug benefit (but did assume that most employers now providing more generous drug coverage to Medicare-eligible retirees would continue to do so).¹⁸

The MMA also specifies that, after 2006, the standard benefit's deductible, initial benefit cap, and catastrophic threshold will increase each year at the projected rate of growth in per capita drug expenditures for the Medicare population. As a result, the drug benefit will, on average, cover about the same share of enrollees' drug costs each year. (See Table 2 for CBO's projections of each of those benefit parameters through calendar year 2013 as well as the associated levels of beneficiaries' cost-sharing liabilities and total drug spending.) CBO estimated that per capita drug spending for Medicare beneficiaries would increase at an average annual rate of nearly 9 percent between 2006 and 2013, by which time the deductible would be \$445, the initial coverage limit would be \$4,000, and the catastrophic threshold for out-of-pocket costs would be \$6,400.

17. For example, beneficiaries who expected to have \$7,100 in drug spending in 2006 would incur \$3,700 in out-of-pocket costs under the standard benefit (\$3,600 for the first \$5,100 in drug spending plus 5 percent of the remaining \$2,000). If they purchased a supplemental policy that provided up to \$1,000 worth of benefits in the doughnut hole, their out-of-pocket costs would fall only to \$3,650 (\$3,600 for the first \$6,100 in drug spending, which is the point at which they would reach the catastrophic threshold, plus 5 percent of the remaining \$1,000). In addition, they would have to pay a premium for that supplemental coverage. Given that enrollees with high drug costs would be most attracted to that package—and could decide each year whether to sign up for the additional protection—that premium would probably be a large share of the maximum \$1,000 benefit. Even if enrollment in that supplemental coverage was broadly representative, its premium would undoubtedly exceed the \$50 in savings on cost sharing that such enrollees would gain.

18. Medigap policies that cover cost sharing for other Medicare benefits are prohibited from including supplemental drug coverage for Part D enrollees, so enrollees who desire such coverage will have to obtain it from another source (such as a former employer or their Medicare drug plan). CBO estimated that about 8 percent of Part B enrollees currently have an individual medigap policy that includes drug coverage. If they chose to sign up for Part D, those beneficiaries would be allowed to enroll in another medigap policy or in a modified version of their current policy that did not provide drug coverage.

Delivery Mechanism. Under the MMA, Medicare will not pay directly for drugs provided to its enrollees. Instead, private entities are expected to deliver Part D benefits and will be paid partly on the basis of their expected costs and partly on their actual costs for doing so. As a result, CBO's estimate of federal costs considered what types of entities would participate as drug plans and what sorts of costs they would incur. In particular, CBO assumed that plans' costs would be related to the degree of financial risk they would bear. Consequently, CBO sought to model the effects of the MMA's provisions on the level of risk that the plans would generally be asked to assume; then, taking into account the provisions allowing drug plans to accept lesser degrees of risk under certain circumstances, CBO estimated the probability that beneficiaries would be enrolled in plans bearing those differing levels of risk, both initially and over time.

Subject to the approval of HHS, various entities could provide Part D benefits. Beneficiaries who received their Part A and Part B benefits through a private health insurance plan, such as a health maintenance organization or preferred provider organization under the renamed Medicare Advantage program, generally would obtain their drug coverage through that plan. (Medicare Advantage will take the place of the existing Medicare+Choice program.) Those enrolled in the traditional fee-for-service Medicare program would generally obtain drug coverage through a prescription drug plan that provided only their Part D benefits. CBO assumed that such plans would probably combine the attributes of an insurance company and a pharmacy benefit manager (PBM), but a wide array of organizational arrangements could be allowed. Once enrolled in Part D, beneficiaries could also switch among plans annually, and those plans would be responsible for providing all covered benefits and tracking each enrollee's total drug costs for the year. Although Medicare Advantage drug plans could have a service area as small as a county, prescription drug plans would have to serve an entire region. (The MMA encourages but does not require HHS to divide the country into at least 10 but no more than 50 regions.)

Provisions for Full-Risk Plans. In general, prescription drug plans and Medicare Advantage drug plans would be expected to assume insurance risk in delivering Part D benefits. They would submit bids reflecting their expected costs of providing those benefits and would largely be paid on the basis of those bids (subject to review by HHS). Thus, they would stand to profit if their costs of

Table 2.**Key Features of the Standard Drug Benefit Under the Medicare Modernization Act, Calendar Years 2006 to 2013**

(Dollars)

	2006	2007	2008	2009	2010	2011	2012	2013
Annual Deductible	250	275	300	325	350	380	410	445
Average Coinsurance Between Deductible and Initial Coverage Limit (Percent)	25	25	25	25	25	25	25	25
Initial Coverage Limit								
Program spending at limit	1,500	1,646	1,808	1,946	2,115	2,265	2,460	2,666
Beneficiary spending at limit	<u>750</u>	<u>824</u>	<u>903</u>	<u>974</u>	<u>1,055</u>	<u>1,135</u>	<u>1,230</u>	<u>1,334</u>
Total spending at limit	2,250	2,470	2,710	2,920	3,170	3,400	3,690	4,000
Coinsurance Between Initial Coverage Limit and Catastrophic Threshold (Percent)	100	100	100	100	100	100	100	100
Catastrophic Threshold								
Out-of-pocket spending at threshold	3,600	3,950	4,350	4,650	5,050	5,450	5,900	6,400
Total spending at threshold ^a	5,100	5,596	6,158	6,596	7,165	7,715	8,360	9,066
Coinsurance above threshold (Percent) ^b	5	5	5	5	5	5	5	5

Source: Congressional Budget Office.

Note: Benefit parameters shown here reflect the Medicare Modernization Act's rounding rules.

- a. Represents total spending at the catastrophic threshold for individuals without other drug coverage.
- b. For 2006, cost sharing will be the greater of 5 percent coinsurance or a copayment of \$2 (for generic drugs and preferred brand-name drugs with generic competitors) or \$5 (for other drugs, including all brand-name drugs without generic competitors). After 2006, the \$2 and \$5 amounts will be indexed to per capita drug costs for the Medicare population.

providing benefits turned out to be lower than expected but would lose money if their costs exceeded expectations. Such a system could provide strong incentives for cost control. But if drug plans were paid only a single and fixed amount per enrollee that was set at the beginning of the year—and thus assumed all financial risk for providing covered benefits—they would also have very strong incentives to avoid enrollees with high drug spending (especially since the same enrollees might incur high drug costs year after year). At the same time, the range of drug plans' potential profits or losses could be large given the uncertainty that surrounds predictions of their costs of providing this new benefit—particularly in the initial years of its operation—and companies might be either unwilling to accept that degree of financial risk or unable to insure against it (through private reinsurance or other mechanisms) at a reasonable cost. Policymakers might also be concerned about the potential for windfall profits if plans' costs turned out to be substantially lower than had been projected.

To mitigate those concerns, the MMA included two sets of provisions that limit the degree of insurance risk that plans would face and that reduce their incentives to avoid the highest-cost enrollees:

- *Individual-Level Reinsurance.* Federal reinsurance payments would cover 80 percent of total drug costs actually incurred once a beneficiary reached the catastrophic threshold on out-of-pocket costs. From that point on, drug plans would thus bear about 15 percent of those costs, while beneficiaries would be liable for about 5 percent.¹⁹

19. The portion of federal subsidy payments that were made to drug plans on a capitated basis would also be adjusted for risk to reflect the expected costs of enrollees based on their health status or other characteristics. However, the adjustment would be made in a manner that was budget neutral overall. Those capitated, or "direct," subsidies are discussed further below.

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■ *Aggregate “Risk Corridors.”* After subtracting reinsurance payments, drug plans that experienced benefit costs that were somewhat higher than they had expected would see an increasing share of those costs covered by additional federal payments, whereas plans with benefit costs that were somewhat below expected levels would essentially have to reimburse Medicare for a corresponding share of the savings. The thresholds of the risk corridors would be relatively narrow in 2006 and 2007 but would double beginning in 2008 and could be increased further by HHS after 2011. (The mechanics of the risk corridor system, how it relates to the MMA's other risk-abatement mechanisms, and the approach that CBO used in estimating its impact on program costs are discussed in the appendix.)

The MMA set no limit on the number of drug plans that could participate if they were willing to accept the full statutory levels of financial risk that resulted from those reinsurance and risk corridor mechanisms. The law specified that at a minimum, though, all Medicare beneficiaries should have a choice of at least two drug plans—one of which could be part of an integrated health plan under the Medicare Advantage program. Thus, the minimum number of prescription drug plans that are supposed to be available to enrollees in the traditional fee-for-service Medicare program is one in areas where a drug plan is offered via Medicare Advantage and two otherwise.

Provisions for Limited-Risk Plans. In case the number of PDPs that are willing to accept full risk in a given area is not sufficient, the MMA provides two mechanisms designed to ensure that beneficiaries have a plan available to them through which to get their drug coverage.

■ *Reduced-Risk Plans.* PDPs that were willing to accept some insurance risk could submit bids that provided for narrower risk corridors in order to reduce (but not eliminate) the risk they would face. Those reduced-risk bids would not be considered, however, unless the number of full-risk plans approved for an area was insufficient to meet the access requirements. If reduced-risk bids were considered, only one or two could be approved (depending on the number of other plans available in the area), with priority generally given to plans willing to accept the most risk.

■ *Fallback Plans.* In case there are not enough plans willing to bear insurance risk (either on a full-risk or reduced-risk basis) in an area, HHS would contract with another organization—designated as a fallback plan—to offer the prescription drug benefit in that area on a “performance-risk” basis.²⁰ One fallback plan would be chosen for each region of the country through a competitive bidding process; however, it would be allowed to enroll members only in the event that too few plans bearing insurance risk were available. At other times, the fallback plan would essentially be on call.

Probability of Enrollment in Limited-Risk Plans. Because of those provisions, CBO assumed that all Medicare beneficiaries would have access to prescription drug coverage under the MMA. Nevertheless, CBO had to estimate the probability that beneficiaries would be enrolled in reduced-risk or fallback plans. That estimate sought to account for several competing considerations.

■ *Factors Increasing Enrollment Probability.* In general, CBO assumed that the easier it was for drug plans to participate as reduced-risk or fallback plans, the greater the likelihood that such plans would be available and thus the higher the expected share of enrollees in those plans. For example, the greater the number of risk-bearing plans that the law requires, the greater the odds that an insufficient number of full-risk bidders will step forward—thus triggering the reduced-risk and fallback provisions. Similarly, the more opportunities that plans have to enroll and retain members while operating on a limited-risk basis, the more attractive it will be to operate as such a plan.

20. With performance risk, the organization would be reimbursed for all costs it incurred in providing benefits and thus would not bear insurance risk, but a portion of its administrative fee would be tied to certain performance requirements. The MMA specified that those requirements should include the following measures: containing costs to Medicare and enrollees “through mechanisms such as generic substitution and price discounts”; providing “quality programs that avoid adverse drug reactions and overutilization and reduce medical errors”; and providing “timely and accurate” customer service and “efficient and effective benefit administration and claims adjudication.” (See section 1860D–11(g)(5) of the Social Security Act, as amended.)

■ *Factors Reducing Enrollment Probability.* Conversely, mechanisms that encouraged companies seeking to participate in Part D to bear the statutory level of risk—or that made it easier for such companies to displace reduced-risk and fallback plans—would tend to limit the availability of such plans and thus would reduce the expected share of enrollees in those plans, both initially and over time. For example, because reduced-risk plans could be displaced if enough full-risk plans submitted acceptable bids, those reduced-risk plans would have a strong incentive to accept full risk as quickly as possible. Similarly, entities such as PBMs that served as fallback plans in one area could not participate as part of a risk-bearing PDP in another area of the country at the same time and could not participate as part of a risk-bearing PDP in the same area in the following year—factors that would make it less attractive to be a fallback plan.

CBO also assumed that the probability of enrollment in reduced-risk and fallback plans would generally decline over time as uncertainty surrounding the cost of providing the benefit diminished.

After analyzing the specific provisions of the MMA, CBO estimated that the expected share of Part D participants enrolled in reduced-risk plans or fallback plans would be about 18 percent in 2006, declining to about 5 percent by 2013. (In other words, about 82 percent of enrollees would be in full-risk plans in the first year of the benefit, increasing to about 95 percent by the end of the budget window.) The percentages represent the likelihood that all enrollees will be in full-risk drug plans and not the share of the population that will be covered by such plans. Although it is possible that full-risk plans will emerge in some regions and not others, CBO did not ascribe an important role for locality per se in the outcome (except insofar as the availability of a Medicare Advantage drug plan would affect the number of prescription drug plans needed in an area to avoid triggering the reduced-risk or fallback provisions).

More generally, in considering whether and to what extent risk-bearing drug plans would participate, CBO assumed that the kind of local disparities that have historically been seen in the Medicare+Choice program would probably not be replicated—largely because the drug benefit program would differ from the Medicare+Choice

system in two important respects. (Medicare+Choice plans are currently available to about 60 percent of beneficiaries, primarily those living in urban areas.) First, the only local network of providers that a drug plan would have to establish would be a network of retail pharmacies, which CBO understood was already in place nationwide. By contrast, the need to establish a network of doctors and hospitals could significantly constrain private health plans seeking to provide Medicare's current benefits, at least in many areas of the country. Second, as discussed further below, the payment system for the drug benefit would base federal subsidies on the average costs of drug plans, not an external reference point. As a result, those subsidies would automatically adjust to reflect faster or slower growth in the average costs of providing the drug benefit, so that efficiently run plans could expect to cover their costs while still offering relatively attractive premiums to enrollees. By contrast, payment rates for Medicare+Choice plans are based on statutory formulas that have not kept up with plans' rising costs (even though those payment rates have often exceeded the costs of providing services in the traditional fee-for-service program, with its administered pricing systems for providers). As a result, many private plans have withdrawn from the Medicare+Choice program in recent years.

Gross Drug Savings. The shares of beneficiaries expected to enroll in differing types of plans affected CBO's cost estimate because the agency assumed that plans bearing more financial risk would have stronger incentives to control drug spending (but would also incur other administrative costs in doing so). Having established the probability that beneficiaries would enroll in different types of plans, CBO then analyzed the degree of financial risk and competition that those plans would face, took into account any constraints that the MMA placed on their efforts to control costs, and generated a summary statistic for the gross level of savings that the program would yield relative to current spending levels. That summary statistic was designed to encompass all of the dynamics that would occur as beneficiaries sorted themselves among the available drug plans and was applied in a manner that accounted for the degree of cost management already reflected in beneficiaries' current spending levels.²¹

21. For additional discussion of the effects of different delivery mechanisms on cost containment, see Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare*, pp. 22-29.

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Incentives for Cost Management. To assess the relative risk that full-risk drug plans would face under the MMA, CBO analyzed the extent to which their actual costs might deviate from the levels they assumed when submitting their bids the previous year. Such deviations could arise from unanticipated changes in drug spending growth generally—such as faster or slower adoption of new brand-name drugs or generic competitors—or from unexpectedly favorable or adverse selection in specific drug plans. In the initial years of the drug benefit, there would be additional uncertainty about what level of spending to assume for an average enrollee. CBO's modeling took into account the random fluctuations that could occur in each of those variables. The degree to which the resulting deviations between actual and expected costs would generate higher or lower reinsurance payments or would yield payments to or from drug plans via the risk corridor system was then factored into the analysis. CBO's assessment of the incentives for cost management also took into account the extent to which beneficiaries would be exposed to the cost differences among drug plans—as expressed through premium levels and cost-sharing requirements. Those differences would affect the degree and nature of competition among plans and their resulting systemic incentives to control costs.²²

Tools for Cost Management. How effectively PDPs could control Medicare drug costs would also depend on whether and to what extent they were allowed to use the various tools at their disposal, such as:

- Enforceable limits on the number and types of drugs included in their “formulary,” or list of covered drugs;
- Variable, or tiered, cost sharing among the drugs included in the formulary, to encourage beneficiaries to use less expensive generic drugs or to switch to similar but lower-cost preferred drugs for which price discounts had been negotiated; and

- Limits on the number and types of pharmacies through which coverage for prescriptions could be obtained.

In general, drug plans can obtain the greatest price discounts for drugs that have close substitutes by giving one of them “preferred” status—thereby allowing that drug's manufacturer to increase its sales volume (at the expense of its competitors) to offset a lower price per unit.²³ Similarly, drug plans can obtain discounts from pharmacies included in their network by steering customers to those pharmacies. Another way they can often lower their costs and achieve greater compliance with their formulary is through the use of mail-order pharmacies. As a result, the prices of drugs used by individuals with drug coverage (combining what they pay out of pocket with the costs covered by their health plan) are usually less than the prices faced by comparable but uninsured individuals paying full retail prices. At the same time, a trade-off generally exists between the ease with which enrollees can obtain the drugs of their choice and a plan's effectiveness in managing drug spending.

The MMA included a number of rules about how drug benefits would be provided, several of which could restrict plans' use of cost-management tools. One set of requirements would primarily affect whether and how beneficiaries could get coverage for specific drugs.

- Plans would have to include in their formulary at least two drugs within each “therapeutic class” (set of medications) that could be substituted in the treatment of a condition or disease (but they would not have to cover all drugs in each class).
- After an outside entity (U.S. Pharmacopeia) had established a standard set of therapeutic classes, drug plans could deviate from that system, but if they did, they would be more vulnerable to rejection by HHS on the grounds that they had designed their benefit to discourage sicker beneficiaries from enrolling.

22. For example, if beneficiaries had been given a choice of drug plans but their premiums did not reflect the overall costliness of the plan they joined and if they faced low coinsurance rates that largely insulated them from drug price levels, then competition among plans would probably focus on offering more generous benefits and would not encourage the use of cost-saving mechanisms.

23. In dollar terms, discounts are often largest for brand-name drugs that have brand-name competitors. In percentage terms, discounts are often largest for generic drugs and brand-name drugs with generic competitors, but such drugs are generally less expensive and constitute a smaller share of total drug spending.

- Subject to certain rules regarding their development, plans could establish formularies that not only limited coverage to certain drugs but also designated some drugs as preferred (and thus subject to lower cost sharing) or even instituted various tiers of coverage (subject to the overall constraints on beneficiary cost sharing for covered drugs).
- Before beneficiaries satisfied the deductible and while they were in the benefit's doughnut hole, they would have to be able to buy their drugs at the same negotiated prices on which plan costs for providing covered benefits were based.
- Beneficiaries could request coverage of a noncovered or nonpreferred drug on the terms applicable to a covered or preferred drug if their doctor determined that the covered or preferred drug would not be as effective or would have adverse side effects. If the use of such nonformulary drugs was not successfully appealed, however, spending on them would not count toward the benefit's deductible, initial coverage limit, or catastrophic threshold.

A second set of MMA requirements regarding how benefits would be provided would primarily affect which pharmacies enrollees could use to get their prescriptions filled.

- Drug plans could establish a network of preferred pharmacies and could use differential cost sharing to encourage beneficiaries to use those pharmacies, but that network would have to meet certain requirements regarding accessibility. (For example, 90 percent of urban Medicare beneficiaries would have to have a network pharmacy available within two miles of their home.)
- At the same time, plans would have to allow "any willing pharmacy" to serve their enrollees (though not necessarily as a preferred or network pharmacy), so long as those pharmacies accepted the terms and conditions specified by the drug plan.
- Beneficiaries would have to be allowed to fill prescriptions at a retail pharmacy instead of a mail-order pharmacy, but they could be charged more for doing so.

Taken as a whole, the provisions of the MMA would place some limits on the ability of drug plans to use cost-management tools, CBO concluded. For example, the requirement that cost sharing average about 25 percent for a substantial portion of the benefit would constrain to some extent the price differences that beneficiaries would be likely to see between preferred and nonpreferred drugs, which in turn would limit the ability of plans to steer usage toward lower-cost preferred drugs and to get commensurate discounts for those drugs. Furthermore, CBO judged that the external review process—under which requests to cover excluded drugs or to purchase nonpreferred drugs at the cost-sharing rate for preferred drugs would be automatically reviewed when denied—would make it more costly for drug plans to enforce (and thus less likely to impose) a strict formulary. Plans would also have to cover at least two drugs in each class of similar therapies, but their ability to define those classes broadly (so as to limit coverage to selected drugs) would be circumscribed.

At the same time, CBO assumed that the MMA's pharmacy network provisions would not substantially impede plans' efforts to control costs. Even though the MMA would require drug plans to allow any willing pharmacy to fill enrollees' prescriptions, it would give drug plans broad authority to vary reimbursement rates and beneficiaries' out-of-pocket payments between network and other participating pharmacies in order to discourage participation by and use of nonnetwork pharmacies.²⁴ Similarly, the requirement that beneficiaries be allowed to use retail rather than mail-order pharmacies would also provide considerable latitude for plans to use differences in cost sharing to steer beneficiaries toward the distribution channel that was least costly for the plans.²⁵

24. Specifically, paragraph (c)(1) of section 1860D-4 of the Social Security Act, as amended, specifies that nothing in that section "shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation."

25. Paragraph (b)(1)(D) of section 1860D-4 allows beneficiaries to fill any prescription at a retail pharmacy rather than a mail-order pharmacy but also allows drug plans to impose "any differential in charge" in such cases. CBO interpreted that language to mean that drug plans could impose an additional charge for using a retail pharmacy that exceeded the strict difference in transaction costs between retail and mail-order pharmacy services in order to encourage beneficiaries to use mail-order pharmacies.

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Overall Impact. To summarize the effects of incentives and tools on cost management, CBO sought to estimate the gross drug savings that would result on average.²⁶ Those gross drug savings represent the degree to which costs would be reduced relative to an unmanaged benefit in which drugs were purchased at full retail price, such as a traditional indemnity insurance plan—a hypothetical but useful reference point. Those savings would result from three types of cost management: negotiating price discounts or rebates from drug manufacturers and pharmacies (net of pharmacy dispensing fees and other claims processing costs); controlling overall drug use; and changing the mix of drugs used.

Following its analysis of the available literature on cost-management techniques as well as discussions with industry and other health care experts, CBO assumed that the maximum level of gross drug savings that could be achieved on average under any circumstances was 30 percent. Achieving that level of savings would require a highly competitive environment, meaningful risk bearing by plans, and substantial freedom to use cost-management techniques. Beyond that point, though, CBO concluded that an average beneficiary would probably not value the savings from joining a lower-cost plan enough to accept the restrictions it would have to impose, nor would additional increments of financial risk elicit further cost control efforts by drug plans. By comparison, CBO estimated that Medicare beneficiaries with employer-sponsored drug coverage experienced gross drug savings of 15 percent, on average, in the 1999-2000 period (the latest years for which detailed spending data on Medicare beneficiaries were available in 2003).²⁷ While those employer plans ultimately bear substantial financial risk in providing drug benefits, they must also balance their interest in limiting costs with their need to provide competitive compensation and to maintain productive relationships with their employees (some of whom are union members covered by collective bargaining agreements). Furthermore, retirees generally are not offered a choice of a drug plan that is separate from their overall

choice of a health plan, so the degree of price competition that occurs is limited.

For the MMA, CBO estimated that the gross drug savings for plans that bore the statutory level of risk would rise gradually from an average of 20 percent in 2006 to an average of 25 percent by 2013, an increase that primarily reflected the evolution of the MMA's risk-sharing arrangements over the budget window. CBO determined that the MMA's risk corridor provisions for the initial years of the benefit would have a meaningful impact on plans' incentives to control spending. By contrast, the ultimate risk corridors provided in the law would have only a negligible effect on cost-management efforts—so gross drug savings estimated for those years primarily reflected the effects of the limits that the MMA would place on the use of cost-management tools. Another key consideration was that, to the extent they arose, full-risk plans would face a highly competitive environment that encouraged beneficiaries to join the lowest-cost plan that met their needs (as discussed further in the section on beneficiaries' premiums). It is important to note, however, that CBO's estimate of gross savings represents savings from managing the drug benefit but not the costs of the mechanisms used to achieve them. It also does not capture the effect that the legislation will have on trends in drug prices, changes in drug use by beneficiaries as a result of changes in their own out-of-pocket costs under the program, or the impact of any exemption from Medicaid's best-price provisions for prescription drugs—each of which was modeled separately.

For many beneficiaries, the effect of cost management on their drug spending will be smaller than the 20 percent to 25 percent savings assumed for individuals who now pay full retail prices and who will enroll in full-risk drug plans. For Part D enrollees whose current drug costs are being managed in some way—primarily those with employer-sponsored or Medicaid coverage—that spending already reflects some degree of gross savings. CBO's estimates took that fact into account and also assumed that any incremental savings would be further attenuated to the extent that those enrollees retained relatively generous supplemental coverage (which would make their spending more difficult to manage). Furthermore, for beneficiaries enrolled in reduced-risk and fallback plans, CBO estimated gross savings averaging 12.5 percent throughout the budget window (somewhat smaller than the 15 percent savings seen for current employer-sponsored drug coverage). In part that estimate reflected the reduced fi-

26. That summary statistic was often referred to as a cost-management factor, or CMEF.

27. Any increases in the average level of gross drug savings since that time or in the future—to reflect additional efforts by employers to control growth in drug spending—would be reflected in the growth rates that CBO applied to drug spending in the 2004-2013 base period.

nancial incentives to control costs that such plans would have, and in part it reflected the less competitive environment in which they would operate.²⁸ Finally, CBO assumed that the gross savings would be offset somewhat by difficulties in allocating and auditing drug discounts and other expenditures (for example, to determine which costs were subject to reinsurance payments or risk corridor transfers).

Other Effects on Drug Prices. CBO's analysis also sought to account separately for various effects that the Medicare drug benefit's provisions could have on drug prices, including responses of drug manufacturers, interactions with the Medicaid best-price provisions regarding prescription drugs, and restrictions on the role that HHS could play in setting drug prices or establishing a drug formulary.

First, CBO assumed that even the most aggressive use of cost-management tools by drug plans would be unlikely to keep prices for some drugs from rising as a result of a Medicare drug benefit. By reducing the cost to consumers of obtaining covered drugs, the new Medicare drug benefit would correspondingly make Medicare enrollees—particularly those who currently do not have prescription drug coverage—less sensitive to drug prices. For instance, if a drug's target population consisted mainly of Medicare beneficiaries and close substitutes for that drug did not exist, the manufacturer could raise the drug's price—or, in the case of a new drug, could enter the market with a higher launch price. The loss in sales resulting from that price hike would not be large enough to reduce the manufacturer's profit, however, because beneficiaries would pay only a portion of that higher price. Preventing such price hikes would be difficult without imposing direct price controls or threatening to deny or delay coverage of the drug. Most drugs, however, face competition from close substitutes, and the most likely effect of a Medicare drug benefit would be modest price increases for the subset of drugs that had patent protection or exclusive marketing rights. CBO modeled that “price effect” as a function of drug spending by enrollees who previously did not have prescription drug coverage, because those who already had generous coverage would have been insulated from full prices even in the absence of legislation.

28. Those plans would still have to compete to be selected by HHS as a reduced-risk or fallback plan.

At the same time, CBO estimated that the cost-sharing requirements of the MMA would limit the extent of that price effect. Beneficiaries who did not receive the low-income subsidies would still face the full negotiated price of the drugs they purchased before they reached their deductible and when their spending fell between their initial coverage limit and the catastrophic threshold. Even after they reached the catastrophic threshold, beneficiaries would generally face some coinsurance and thus would not be completely insulated from price increases. In light of those factors, CBO estimated that drug costs for Medicare beneficiaries would ultimately be 3.5 percent higher, on average, because of the price effect, with the impact phasing in over the first 10 years of the benefit. The extent to which the entities delivering the drug benefit would offset those price increases through negotiated discounts or would design cost-sharing requirements to encourage price sensitivity is already reflected in the estimated average level of gross drug savings.

Second, CBO considered the fact that prices negotiated under the Medicare drug benefit would be exempt from Medicaid's best-price provisions. Those provisions essentially require drug manufacturers to charge Medicaid the lowest price paid by any private purchaser for a brand-name drug (after taking into account rebates, discounts, and other adjustments). As a CBO paper on that topic noted, “Medicaid constitutes between 10 and 15 percent of the market for outpatient prescription drugs, [so] pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price.” That report and others have shown that private discounts declined after the Medicaid best-price provisions were implemented in the early 1990s.²⁹

On the basis of that evidence, CBO assumed that the price discounts that Medicare drug plans could negotiate would be greater if they were exempt from the best-price requirements. CBO further assumed that the extent of the additional savings would depend on the gross savings level that the drug plans achieved—because the greater the incentives and tools that a drug plan had to control

29. See Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (January 1996); and General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals Are Uncertain*, GAO/HEHS-97-60 (June 1997).

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costs, the more constraining the best-price provisions would be. CBO also modeled the extent of the savings as a function of Medicaid's remaining market share for prescription drugs (once the Medicare benefit was in place); in the absence of an exemption from the best-price provisions, that market share would also have affected the willingness of manufacturers to provide discounts to Medicare drug plans.³⁰ For the MMA, CBO assumed that—when averaged across all drugs—Medicare drug plans would be able to obtain an additional 1.6 percent price discount in the initial years of the benefit because of the best-price exemption, increasing to an ultimate level of 2.5 percent.

Third, the MMA also included a provision specifying that HHS “may not interfere with the negotiations between drug manufacturers and pharmacies” and prescription drug plans and “may not require a particular formulary or institute a price structure” for covered Part D drugs. For a variety of reasons, CBO assumed that including that “noninterference” provision would neither raise nor lower federal costs significantly. It is not clear that HHS would have taken such steps in the absence of those restrictions. And even if it had, it is not clear that those steps would have appreciably raised or lowered drug spending relative to the levels that prescription drug plans would secure.

Underlying that uncertainty is CBO's assumption that risk-bearing drug plans will obtain substantial savings on their own and in particular will probably do so by establishing relatively narrow lists of lower-cost preferred drugs and steering beneficiaries' use toward those drugs.³¹ For HHS to use the greater market share of the entire Medicare population as a source of leverage to secure deeper price discounts and greater cost savings, it would probably have to threaten similar exclusions and limitations on coverage for that entire population—a threat that could be difficult to make credible given the potential impact on stakeholders. (Other policy objectives, such as encour-

aging the development of new drugs, also could be adversely affected as a result of securing deeper discounts.) Alternatively, HHS could encourage or require preferred status for a larger number of drugs than private drug plans would otherwise offer. Although that approach could help meet other objectives (such as enhancing beneficiaries' access to those additional drugs), it would increase the cost of providing the drug benefit. On balance, then, CBO concluded that retaining the noninterference provision (or by the same token, striking it) would have a negligible effect on the expected level of federal spending.³²

Other Effects on Drug Use. CBO also assumed that enrollees' total spending on prescription drugs would change as a result of the insurance coverage provided by the new Medicare benefit, depending on the relative generosity of pre- and postpolicy drug coverage for each enrollee. In other words, enrollees' overall drug use under the MMA would rise or fall along with changes in their out-of-pocket costs. That “use effect” took into account all of the factors discussed above that would affect enrollees' out-of-pocket costs—those that changed enrollees' total spending on drugs (such as the price effect or gross savings from cost management) and those that simply changed the share of that spending for which enrollees themselves paid (because of the benefit's design or any supplemental coverage they had).

Specifically, CBO assumed that enrollees' spending for prescription drugs would rise by as much as 3 percent for every 10 percent drop in their out-of-pocket costs.³³ The estimated change in enrollees' out-of-pocket costs took into account their current coverage and whether they would enroll only in the basic Medicare benefit or would participate in the low-income subsidy program as well (as described below). Among enrollees in stand-alone prescription drug plans and Medicare Advantage drug plans, that assumption about the induced demand for drugs increased CBO's estimate of drug spending by approximately 9 percent. That is, total drug consumption was

30. Although Medicaid's share of total U.S. drug spending will decline under the MMA because spending on dual eligibles will shift to Medicare, Medicaid will still purchase a significant amount of drugs on behalf of its other enrollees.

31. In the process, drug plans could secure deeper price discounts for those preferred drugs in exchange for the increase in their sales volume. Even without such discounts, though, simply shifting use to lower-priced drugs—including generic drugs—would probably constitute an important source of savings.

32. For additional discussion of this issue, see Congressional Budget Office, *Letter to the Honorable William H. Frist, M.D., regarding CBO's estimate of the effect of striking the “noninterference” provision as added by P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (January 2004); and Congressional Budget Office, *Letter to the Honorable Ron Wyden regarding the authority to negotiate prices for single-source drugs for Medicare beneficiaries* (March 2004).

projected to be about 9 percent higher each year than it would have been in the absence of a demand response.

Other Administrative Costs. CBO's estimate of covered drug costs included certain costs that could be considered purely administrative (such as dispensing fees paid to pharmacies and other costs of processing claims), but the agency accounted separately for expenses that drug plans would incur for marketing, member acquisition, and member retention as well. In addition, CBO assumed that plans would incur costs as a result of having to bear financial risk—whether to offset the costs of purchasing private reinsurance policies or to build up their own reserves in case their costs exceeded expectations. Specifically, CBO estimated that plans bearing the statutory level of risk would require a premium in proportion to the degree of risk they faced; that premium would be higher in the initial years of the benefit (when there was greater uncertainty about its costs) than in later years. For reduced-risk and fallback plans, however, such costs would be cut or absent. Overall, CBO estimated that drug plans' other administrative costs would add about 11 percent to the costs of providing covered drug benefits

in 2006, with that increment declining to about 6 percent in 2013.³⁴ (Those percentages represent weighted averages of the administrative costs for full-risk drug plans and for reduced-risk and fallback drug plans.)

Summary of Effects on Gross Benefit Costs. As discussed above, CBO applied several key factors to estimate gross benefit costs (see Table 3). The net effect of those assumptions can be seen in levels of average drug spending under the MMA as well as the average gross costs of providing the standard drug benefit (see Table 4). Overall, the various adjustments that CBO made to baseline drug spending reduced the amount of spending that would be subject to coverage by about 0.5 percent in 2006 and about 5 percent in 2013.³⁵ Applying the MMA's benefit design to that spending generated an average cost for covered benefits of \$1,482 in 2006, rising to \$2,568 in 2013. Including administrative costs and multiplying by the number of participants in each year yielded estimates of total calendar year obligations that would be incurred. CBO then converted those estimates to outlays made during the fiscal year, projecting that payments to prescription drug plans and Medicare Advantage plans for providing the basic Medicare drug benefit would total \$507 billion for the 2006-2013 period (see Table 1 on page 2).

CBO's estimates of average cost-sharing obligations and average out-of-pocket costs for Part D enrollees are also shown in Table 4. The estimate of average liability for cost sharing is simply the difference between average spending under the benefit (\$2,878 in 2006) and average covered benefits (\$1,482 in 2006). That liability figure does not take into account any supplemental coverage that enrollees might have (through the low-income subsidies or a former employer, for instance). Beneficiaries'

33. In economic terms, CBO started with the assumption that the arc elasticity of demand for prescription drugs was -0.3 (in which the denominator used to calculate the percentage change in drug spending and out-of-pocket costs was the average of the pre- and postpolicy levels). That elasticity estimate reflected a review of the available studies on drug spending as well as CBO's own internal analysis using MCBS data on drug spending by Medicare beneficiaries. Although demand elasticities usually relate a percentage change in quantity to a percentage change in price, total spending and out-of-pocket costs were used instead, both to reflect the results of the literature and to comport more closely with CBO's focus on spending (which could change if an individual switched to a more or less expensive medicine even though the quantity consumed was held constant). At the same time, estimates based on the responses of individuals with less generous drug coverage might not be applicable for beneficiaries with very generous drug coverage. CBO thus applied an adjustment factor based on the portion of an individual's cost-sharing liabilities that was covered by third parties, which ranged from 1 (for beneficiaries with no additional drug coverage beyond the basic Medicare benefit) to zero (for beneficiaries who would face no cost sharing before or after the Medicare benefit was implemented). In other words, the effective arc elasticity used was -0.3 for otherwise uninsured enrollees and a smaller amount for those with some form of supplemental drug coverage. For a recent summary of elasticity estimates for drug spending, see Mark Pauly, "Medicare Drug Coverage and Moral Hazard," *Health Affairs*, vol. 23, no. 1 (January/February 2004), p. 117.

34. Whether those costs offset administrative costs that would have been incurred in providing drug coverage in the absence of a Medicare benefit or instead represented added costs was not a significant consideration in the cost estimate but could affect estimates of total U.S. spending in the health or drug sectors.

35. To generate a cost estimate, CBO focused on drug spending that would be covered under the Medicare benefit. To the extent that drug plans reduced costs by limiting coverage to preferred drugs but beneficiaries continued to purchase drugs that were not covered, average drug spending for participants would be greater than the amount shown here.

18 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table 3.****Key Factors Used in CBO's Estimate of Gross Drug Costs per Drug Benefit Participant, Calendar Years 2006 and 2013**

(Percent)	2006	2013
Factors Reducing Gross Costs		
Gross Drug Savings Relative to Spending for an Unmanaged Drug Benefit		
Average for full-risk drug plans	20.0	25.0
Average for reduced-risk or fallback drug plans	12.5	12.5
Average Reduction in Spending as a Result of Exemption from Medicaid's Best-Price Provision	1.6	2.5
Factors Increasing Gross Costs		
Average "Price Effect"	0.3	2.8
Average "Use Effect"	9.0	9.3
Administrative Costs as a Share of Benefit Costs	10.7	5.6
Memorandum:		
Probability of Enrollment		
Full-risk drug plans	82	95
Reduced-risk or fallback drug plans	18	5

Source: Congressional Budget Office.

Note: See the text for an explanation of the terms used here.

average out-of-pocket costs—accounting for such other drug coverage but excluding their Part D premiums—are also relevant to the cost estimate because of the use effect described earlier. CBO estimated that for 2006, average out-of-pocket costs would fall from \$1,257 in the absence of a Medicare drug benefit (43 percent of average drug spending) to \$792 under the MMA (28 percent of average drug spending).

Beneficiaries' Premiums

The share of gross benefit costs that will be covered by beneficiaries' premiums and the corresponding subsidies will have a large effect on the federal costs of providing a drug benefit under Medicare. Not only will the premium subsidies determine how gross costs are allocated between enrollees and the government, but they will also affect participation in such a voluntary program. This section examines how those premiums and the corresponding federal subsidies are established under the MMA and then shows how CBO estimated and accounted for total premium payments.

Under the MMA, the premium that an individual beneficiary pays for Part D benefits is not set in law and will depend on which drug plan he or she joins. Drug plans will submit bids to reflect their expected costs per beneficiary of providing basic drug coverage, and HHS will calculate a national average of those bids. HHS will then set an average beneficiary premium to cover 25.5 percent of expected average costs per enrollee. Plans with bids below the national average will see a corresponding reduction in their enrollees' premiums, whereas plans bidding above the national average will see a commensurate increase. Under that mechanism, drug plans will have strong incentives to keep their bids low to attract enrollees, and beneficiaries will have to consider whether the extra premium of a more costly plan is worth paying—two factors that affected CBO's assumption about the gross savings that drug plans would achieve on average.

Once beneficiaries' premiums for each drug plan are set, the remaining portion of a drug plan's expected costs will be covered by federal subsidies, which will come in two forms. As discussed above, reinsurance payments will

Table 4.**Estimated Costs for Drug Benefit Participants, Calendar Years 2006 and 2013**

(Dollars)	2006	2013
Average Drug Spending by Projected Participants		
Without a Medicare drug benefit	2,894	5,268
Under the Medicare drug benefit ^a	2,878	5,017
Average Gross Medicare Costs per Participant for Basic Drug Benefits		
Excluding plans' administrative costs	1,482	2,568
Including plans' administrative costs ^a	1,640	2,713
Average Cost-Sharing Liability	1,396	2,448
Average Out-of-Pocket Costs		
Without a Medicare drug benefit	1,257	2,312
Under the Medicare drug benefit	792	1,392
Memorandum:		
Projected Number of Participants (Millions)	29.0	33.9

Source: Congressional Budget Office.

- a. These figures differ from comparable figures that CBO released in November 2003 because of subsequent refinements in the calculation of spending and costs per participant that do not affect the cost estimate. See Congressional Budget Office, *Letter to the Honorable Don Nickles providing additional information about CBO's cost estimate for the conference agreement on H.R. 1* (November 2003).

cover 80 percent of drug spending incurred once an individual enrollee reaches the benefit's catastrophic threshold. In total, those payments will cover about 27 percent of gross costs for benefits and administrative expenses in 2006, CBO estimated. The remaining subsidy (referred to as the "direct" subsidy) will be set prospectively so that the two subsidies together cover 74.5 percent of the average expected costs for all enrollees in the basic Medicare benefit. In other words, the direct subsidy will cover about 47.5 percent of average costs in 2006, in CBO's estimation—but if in the future the share of costs expected to be covered by reinsurance differs from 27 percent, HHS will be required to adjust the direct subsidy correspondingly to keep the sum of the two subsidies at 74.5 percent. (That adjustment will be made on a purely prospective basis; the direct subsidy is a capitated payment that will not be changed midyear or retroactively if actual reinsurance payments differ from the projections.) The direct subsidy will also be essentially the same regardless

of which drug plan enrollees join, which is why their premium will vary with the total cost of each plan.³⁶

Using CBO's estimates for 2006, costs for an average plan of about \$137 per month would translate into federal subsidies of about \$102 per month and beneficiaries' premiums of about \$35 per month (see Table 5). To illustrate the impact on beneficiaries' premiums, the table also presents hypothetical submissions by plans that have benefit costs per member per month that are \$10 higher or lower. (CBO did not estimate the likely range of premiums that beneficiaries would actually face across drug plans.) Each plan's expected level of reinsurance pay-

36. The direct subsidy will be adjusted for risk to reflect expected differences in drug costs stemming from differences in health status among enrollees in different plans; it could also be adjusted to account for differences in drug prices in different regions of the country (if HHS determined that such differences were more than minimal). For those reasons, the actual direct subsidy payment per enrollee could differ among drug plans and enrollees.

20 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table 5.****Total Costs, Federal Subsidies, and Beneficiaries' Premiums for Calendar Year 2006 Under Three Illustrative Plans**

(Average amount in dollars per enrollee per month)

	Lower-Cost Plan	Average-Cost Plan	Higher-Cost Plan
Expected Total Costs			
(Benefits plus administrative costs)	127	137	147
Minus Expected Federal Reinsurance Payments ^a	- 34	- 37	- 40
Plan's Bid for Providing Coverage	93	100	107
Minus "Direct" Federal Subsidy	- 65	- 65	- 65
Beneficiary's Premium	28	35	42
Memorandum:			
Premium as a Share of Total Costs (Percent)	22.0	25.5	28.5

Source: Congressional Budget Office.

a. Figures shown here assume that reinsurance payments are a constant percentage of each plan's total costs and represent an average monthly level of such payments (even if actual reinsurance payments are likely to be concentrated toward the end of the calendar year).

ments—here assumed to cover 27 percent of its average costs—would be subtracted from its expected total costs of providing the drug benefit to yield its bid.³⁷ HHS would then calculate an average of those bids (weighted by enrollment) and would set the direct subsidy so that the total subsidies for the average plan covered 74.5 percent of its total costs. The same direct subsidy amount would be provided to the higher-cost and lower-cost plans. As a result, although a portion of the cost differences across plans would be absorbed by federal reinsurance payments, the bulk of the differences would be passed on to beneficiaries through higher or lower monthly premiums. The examples in the table also show that total payments to drug plans are expected to equal the amount that the plans specify in their submissions to HHS (although those amounts are subject to review by

and negotiation with HHS). That is, the sum of the expected reinsurance payment, the direct subsidy, and the beneficiary premium for each plan equals its total expected costs.³⁸

Although beneficiaries' premiums will vary as a result of this subsidy system, CBO did not have to estimate the extent of that variation because, on average, the higher premium payments made by beneficiaries joining higher-cost plans would be offset exactly by reduced premium payments from beneficiaries who join lower-cost plans. Applying the 74.5 percent subsidy to the average costs of providing covered benefits of \$1,640 thus yielded average annual premiums of \$418 in 2006 (about \$35 per month, as shown above); the net federal subsidy would thus average \$1,221. By 2013, when the average cost of providing the basic drug benefit is projected to be \$2,713, the average beneficiary's premium would total \$692 for the year (about \$58 per month); the net federal subsidy would thus be \$2,021 per enrollee. (Premiums grow somewhat more slowly than the benefit's parameters—by about 7.5 percent per year, on average—because

37. Since a lower plan bid will translate into a lower beneficiary premium, this system could appear to provide an incentive for plans to overstate their expected reinsurance payments. If they did, however, their total payments for the year (including the reinsurance payments they actually received) would not cover their costs. Similarly, drug plans would not want to understate their expected reinsurance payments because (if total costs were held constant) the enrollee's premium would be commensurately higher as well, which would discourage enrollment. Thus, plans will have strong incentives to estimate their expected reinsurance payments accurately.

38. To the extent that plans' actual costs diverged from expectations, that difference could yield higher or lower federal reinsurance payments and could trigger transfers under the risk corridor system.

they reflect administrative costs as well as benefit costs.) Multiplying those figures by the projected number of enrollees in prescription drug plans and Medicare Advantage plans, and then converting to fiscal year receipts, yielded the overall estimate of \$131 billion for the 2006-2013 period (see Table 1 on page 2).

Two accounting matters are relevant to the calculation of CBO's estimate for premium collections. First, the MMA will permit beneficiaries to pay the premium for the basic drug benefit either by having it withheld from their Social Security benefit (as is generally done for the Part B premium) or by arranging to pay their drug plan directly. The estimate for premium collections in Table 1, however, is presented as if all participants in the drug benefit chose to have premiums withheld from their Social Security benefits (in which case Medicare would transfer those payments to the drug plans). To the extent that beneficiaries chose to pay plans directly, federal spending for benefits and premium collections would be reduced dollar for dollar and there would be no change in the estimate of the net cost of the Medicare benefit. Second, the figures for premium collections also include the portion of premiums paid by Medicare on behalf of participants in the low-income subsidy system (with those payments also appearing below as a cost of providing the low-income subsidies). Displayed in that way, the difference shown in Table 1 between the payments to drug plans for benefits and administrative costs, on the one hand, and premium liabilities, on the other, represents the net cost for Part D enrollees of the federal subsidies for the basic Medicare benefit—a total of \$377 billion through 2013.

The Employer Subsidy System

Former employers are the single largest source of drug coverage for Medicare beneficiaries today. The extent to which those employers will supplement the Medicare benefit in the future can have important effects on federal costs because of the MMA's true-out-of-pocket provision. (As discussed above, that provision lowers the federal cost of providing the basic drug benefit for enrollees with additional drug coverage because that supplemental coverage delays the point at which enrollees reach the catastrophic threshold for out-of-pocket costs.) Another potential factor that could affect federal costs is the number of employer and union plans that choose to provide Medicare-eligible retirees with qualified drug coverage and receive a subsidy directly from Medicare. In light of those considerations, CBO had to project the prevalence of coverage from employers in the absence of a Medicare

drug benefit and then estimate both the degree to which that coverage would change as a result of the legislation and the mechanism through which it would be subsidized. CBO also had to account for any indirect impacts of the drug benefit on federal tax revenues.

Background. About 30 percent of the enrollees in Medicare Part B are nonfederal retirees who currently receive prescription drug coverage through a former employer, CBO estimated. Their retiree health coverage generally supplements Medicare's benefits for Parts A and B as well. Because Medicare covers a large share of acute medical costs but has not provided an outpatient drug benefit, a sizable share of the current cost of retiree health plans consists of prescription drug spending—as much as 40 percent to 60 percent, by some estimates.³⁹ Although employer-sponsored drug coverage is typically rather generous—providing relatively low cost sharing as well as limits on retirees' out-of-pocket costs—recent growth in drug spending has led employers to take measures to control their health costs, such as raising cost-sharing obligations, requiring retirees to shoulder a larger share of supplemental premiums, or dropping coverage for future retirees. However, CBO did not see strong evidence that current beneficiaries or those who will soon enroll in Medicare have been losing retiree drug coverage in ways that would substantially affect the overall share of beneficiaries with such coverage in the near term.⁴⁰ Thus, CBO

39. See Hewitt Associates LLC, *The Implications of Medicare Prescription Drug Proposals for Employers and Retirees* (prepared for the Henry J. Kaiser Family Foundation, Washington, D.C., July 2000), pp. 1 and 15.

40. For example, one recent study found that the share of Medicare beneficiaries ages 65 to 69 with drug coverage through a former employer declined in the late 1990s. However, that share was still greater than or equal to the share of older Medicare beneficiaries with retiree drug coverage, so the total share of Medicare beneficiaries with such coverage—combining younger and older cohorts—remained virtually constant. See Bruce Stuart and others, "Employer-Sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years," *Health Affairs* Web Exclusive (July 23, 2003), available at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.334v1>. A more recent study indicated that declines in the coverage offered to future retirees over the past few years have applied almost exclusively to newly hired employees and thus would not be likely to affect the share of Medicare beneficiaries with such coverage in the near term. See Henry J. Kaiser Family Foundation and Hewitt Associates, *Retiree Health Benefits Now and in the Future: Findings from the Kaiser/Hewitt 2003 Survey on Retiree Health Benefits* (Washington, D.C.: Kaiser Family Foundation, January 2004).

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assumed that the share of beneficiaries with such retiree coverage would remain at about 30 percent through 2013 in the absence of a Medicare drug benefit, but it also assumed that average cost-sharing liabilities for those beneficiaries would increase at nearly the same rate as overall drug spending.

Options for Employers. Under the MMA, employers would have three broad options from which to choose in determining the extent of the drug coverage they would provide, the mechanism they would use to do so, and the subsidies that would be generated as a result.

Option 1: Wrap Around a Medicare Drug Plan. An employer could have its retirees enroll in a prescription drug plan or Medicare Advantage plan to obtain the basic drug benefit and then contract with that plan to provide supplemental drug coverage to those retirees.⁴¹ If that supplemental coverage was generous, though, even individuals with very high drug costs might never reach the Medicare benefit's catastrophic threshold because they would not incur sufficient out-of-pocket costs themselves. As a result, the costs of providing catastrophic drug coverage would have to be covered by the employer, at least initially (with some portion of those costs passed on to retirees through their premium payments). Even so, a portion of retirees' drug costs would be shifted to Medicare under this option.

Option 2: Provide Drug Coverage Directly and Receive a Subsidy from Medicare. An employer could continue to provide drug coverage itself (or through a health plan or other subcontractor of its own choosing). So long as that coverage was at least as valuable overall as the basic Medicare benefit, the employer could then receive a payment from Medicare to cover 28 percent of each retiree's total drug spending in a specified range. (For 2006, that range would extend from \$250 to \$5,000; in future years, its endpoints would be indexed to per capita drug spending for Medicare beneficiaries.) In addition, that Medicare subsidy payment would receive preferential tax treatment, and such employer plans would be subject to less scrutiny and fewer regulatory requirements than Medicare drug plans would be.

41. That approach would be analogous to the way that employer coverage currently wraps around Medicare's other benefits. Employers could even function as the prescription drug plan for their retirees (and could serve them exclusively) but they would have to be approved by HHS in the same manner as other PDPs were.

Option 3: Drop Drug Coverage for Retirees. An employer could decide not to provide drug coverage for its Medicare-eligible retirees once the Medicare benefit became available (meaning that the employer would neither provide the benefit directly nor supplement the basic benefit offered by a Medicare drug plan).⁴² In that case, affected retirees would presumably enroll in a Medicare drug plan. Assuming that they did not purchase supplemental drug coverage on their own (for reasons discussed above), retirees with high drug spending would probably reach the benefit's catastrophic threshold and thus would trigger federal subsidies to cover most of those catastrophic costs.

Given that employers would reduce their drug costs the most under the third option, it might seem reasonable to conclude that all employers would drop drug coverage for their Medicare-eligible retirees once the Medicare benefit was in place. If employers were seeking only to minimize their drug costs, however, they would probably have dropped drug coverage already, even in the absence of a Medicare drug benefit. Presumably, then, firms that provide drug coverage for retirees today see reasons for doing so and may continue providing such coverage once the Part D benefit is in place. Some firms may have little choice but to continue providing coverage, either because they did not retain the right to modify the health benefits they provide to current retirees or because they must bargain with unions that have been loath to see those benefits reduced. Even without those constraints, employers operating in competitive labor markets must offer a total compensation package that is attractive to workers and may judge that covering health care costs for retirees allows them to reduce their wage bills. The fact that employers' health spending already receives preferential tax treatment also favors that decision.

42. A court decision in 2000 involving retired government workers in Erie County, Pennsylvania, had been interpreted as potentially preventing employers from varying the health coverage they offered to Medicare-eligible retirees and younger retirees. However, the Equal Employment Opportunity Commission has more recently issued draft regulations allowing employers to drop drug coverage only for Medicare-eligible retirees without violating age discrimination laws. (See Robert Pear, "Agency to Allow Insurance Cuts for the Retired," *New York Times*, April 23, 2004.) Had employers been precluded from varying their benefits, that outcome could have discouraged some of them from dropping coverage for Medicare-eligible retirees and could have led others to drop drug coverage for all their retirees once the Medicare benefit was in place.

Table 6.

Employers' Options for Providing Drug Coverage Under the MMA and Resulting Net Medicare Subsidies per Enrollee, Calendar Years 2006 and 2013

(Dollars)

	Average Net Medicare Subsidy per Enrollee	
	2006	2013
Option 1: Employer's Coverage Wraps Around a Medicare Drug Plan	692	1,348
Option 2: Employer Provides Qualified Coverage Directly and Receives a 28 Percent Subsidy Payment from Medicare	766	1,369
Option 3: Employer Drops Drug Coverage	1,201	2,320

Source: Congressional Budget Office.

Notes: The net Medicare subsidy reflects covered drug costs minus beneficiaries' premiums (if any) and excludes payments to drug plans for their administrative costs. Figures for Option 2 represent Medicare payments only and exclude the effective tax subsidy that applies to those payments.

MMA = Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

In general, then, CBO modeled employers' behavior under a Medicare drug benefit as a function of the benefit's overall generosity, any differential in subsidies between the available options (taking into account their effects on tax liabilities), and the degree of administrative complexity involved in each option. That analysis also accounted for the average effect of each option on premium liabilities and cost sharing for retirees. As an example of the role that the benefit's generosity could play, CBO assumed that if the Medicare drug benefit was as generous as the coverage that employers offered to their retirees, then employers would be strongly inclined not to supplement that benefit (in part because dropping coverage in that case would not leave retirees worse off). Although dropping drug coverage might seem like an extreme response if the Medicare benefit was less generous, one recent survey indicated that nearly one-quarter of large employers would take that approach if Medicare offered drug coverage that included a deductible, coinsurance, and catastrophic protection above \$4,000 in out-of-pocket spending—and that response did not factor in any penalty for supplemental coverage.⁴³

Effects on Coverage and Outlays. After analyzing the three basic options available to employers under the MMA, CBO concluded that average Medicare subsidy payments on behalf of retirees would be greatest if employers dropped drug coverage (Option 3). For example, CBO estimated that in 2006, those retirees would receive an average of \$1,619 in covered benefits if they enrolled in a Medicare drug plan and were provided the basic drug benefit with no supplemental coverage. (That estimate took into account the effect on their out-of-pocket costs.) Subtracting the average beneficiary's premium of \$418 for that year would yield an estimated net subsidy from Medicare of \$1,201 under Option 3 (see Table 6). By 2013, the net Medicare subsidy would grow to an average of \$2,320 for retirees whose former employers had dropped drug coverage.

If those retirees were instead provided generous wrap-around coverage by their former employer (Option 1), Medicare's average subsidy payment would fall. (In that case, enrollees would pay essentially the same premium but receive less coverage through Medicare.) Specifically, the net Medicare subsidy would average \$692 in 2006 under that option, CBO estimated, or about half of the subsidy that would be generated if employers dropped their drug coverage altogether. CBO further estimated that the 28 percent subsidy payments from Medicare (Option 2) would be comparable, on average, to the net

43. Henry J. Kaiser Family Foundation and Hewitt Associates, *The Current State of Retiree Health Benefits: Findings from the Kaiser/Hewitt 2002 Retiree Health Survey* (Washington, D.C.: Kaiser Family Foundation, December 2002), pp. 51-53.

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subsidies that retirees would generate if they enrolled in a Medicare drug plan and retained a generous wraparound policy from their employer (Option 1).⁴⁴ In other words, those Medicare payments to employer and union plans would also be substantially lower, on average, than the net subsidies for retirees whose employers dropped drug coverage (Option 3). Those payments to employer and union plans would be accorded favorable tax treatment, increasing the attractiveness of that option somewhat. Even so, the disparity in Medicare subsidies between Option 3 and the other two options would grow over time.

On the basis of that analysis, CBO concluded that the difference in subsidies under the MMA would give employers a new financial incentive to drop prescription drug coverage for their Medicare-eligible retirees once the drug benefit became available. In essence, the MMA's true out-of-pocket provision would reduce the extent to which federal spending substituted for, or "crowded out," employers' spending on drugs, but it also would penalize supplemental drug coverage sponsored by employers.⁴⁵ CBO further assumed that some employers would respond to that incentive to drop coverage. As a result, CBO estimated that 2.7 million Medicare-eligible retirees who would have had relatively generous employer drug coverage in 2006 in the absence of a Medicare drug benefit would enroll in Part D but would see their former employer decide not to supplement its basic benefits. That figure represents about 23 percent of projected participants in the drug benefit who would have had such coverage from a nonfederal source, or about 17 percent of all Part B enrollees who CBO projected would have had some form of employer-sponsored drug coverage in the absence of a Medicare drug benefit.⁴⁶ CBO assumed that the affected retirees would enroll in a Medicare drug plan, with their former employer potentially "cashing them out" or at least choosing to pay their Part D premium as a means of compensation. (Federal costs for those enrollees

were included above in the estimate of payments to Medicare drug plans.)

At the same time, CBO assumed that nearly all of the remaining retirees with relatively generous employer-sponsored drug coverage from a nonfederal source would see their employer take the 28 percent subsidy payment from Medicare, both because of its tax advantages and for reasons of administrative simplicity.⁴⁷ The number of beneficiaries covered by the 28 percent subsidy would thus rise from 8.2 million in calendar year 2006 to 9.5 million by 2013, CBO estimated. The estimate of \$71 billion in subsidy payments to qualified employer and union drug plans over 10 years (see Table 1 on page 2) reflects both the number of participants and the share of those retirees' drug spending that is projected to fall in the covered range.⁴⁸

Effects on Revenues. Although employers can deduct as a business expense the costs that they incur in providing health benefits to their employees and retirees, those costs are not included in those individuals' taxable income—which results in a considerable "tax expenditure" for employer-sponsored health benefits. Any legislation that affects employers' health costs thus has the potential to change federal revenue collections. In general, CBO as-

44. Because participants in the employer subsidy system would pay no premium to Medicare, the figures for the net Medicare subsidy under Option 2 also represent CBO's estimate of the average payment to employer and union plans under that system.

45. For employers who chose to receive the 28 percent subsidy payment from Medicare, that payment system would not penalize additional drug coverage at the margin. However, the lower average subsidies in that system would still provide an incentive to forgo that option and drop drug coverage.

46. For a further discussion of the denominators used to calculate those percentages, which differ primarily in their treatment of active workers and federal retirees enrolled in Part B, see Congressional Budget Office, *Letter to the Honorable William "Bill" M. Thomas regarding Medicare beneficiaries who receive health insurance provided by employers* (November 2003) and *Letter to the Honorable Don Nickles*.

47. CBO assumed that a very small percentage of employers would find it advantageous to have some or all of their retirees enroll in a prescription drug plan or Medicare Advantage drug plan and wrap around the basic Medicare drug benefit that those plans would provide. CBO also assumed that beneficiaries with employer coverage who were eligible for the low-income subsidies and wanted to enroll in them would also choose to enroll in a prescription drug plan or Medicare Advantage drug plan to receive the low-income subsidy benefits. The MMA does not include a provision allowing low-income subsidy payments to be made to employers that are receiving the 28 percent subsidy payments.

48. Because the net costs to Medicare are similar whether employers receive the 28 percent subsidy payment or instead wrap around the basic drug benefit provided by a Medicare drug plan, net federal outlays (including payments to Medicare drug plans for their administrative costs) would be comparable if the majority of employers chose Option 1 instead of Option 2.

sumed that savings to employer-sponsored plans on their health costs would raise federal revenues by shifting the composition of total compensation packages for employees and retirees toward taxable forms of income (wages and pensions) and away from nontaxable health benefits. That assumption again reflects the view that employers must provide compensation that is commensurate with workers' output in order to attract and retain workers.

Under the MMA, employers that dropped drug coverage would see their health costs decline substantially, whereas employers that received subsidy payments directly from Medicare or wrapped around a Medicare drug plan would see a partial reduction. By themselves, those effects would have led CBO to estimate an increase in federal revenues of about \$25 billion over the 2004-2013 period. However, the MMA also excluded the payments under the 28 percent subsidy system from income taxation, while still allowing employers a tax deduction for the entire portion of retirees' drug costs that they bear (an approach that is sometimes referred to as a "super-credit," in that it essentially provides both a partial tax credit and a deduction for the same expenditures). Accordingly, CBO estimated that those tax preferences would reduce revenue collections by about \$18 billion over the same period. The \$18 billion figure thus represents CBO's estimate of the tax expenditure that would result from the MMA's preferential tax treatment of those subsidy payments. On balance, then, CBO estimated that the MMA's prescription drug provisions would result in an increase of \$7 billion in federal revenues through 2013.⁴⁹

There are two reasons why it would be inappropriate to add together the \$18 billion tax expenditure and the \$71 billion in direct payments to generate a total figure of \$89 billion for subsidies to employers. First, the tax expenditure represents the extent to which that \$71 billion in payments would ultimately have been recaptured through the tax system had it not been for the income-tax exclusion; the tax expenditure can thus be thought of as maintaining the value of those payments but not augmenting

it. Second, that approach does not take into account the subsidy payments that would be made on behalf of retirees who would otherwise have had employer-sponsored drug coverage and who enrolled in a prescription drug plan or Medicare Advantage drug plan (whether as their only source of drug coverage, in conjunction with an employer wraparound policy, or to take advantage of the low-income subsidies). Those indirect subsidy payments also cover spending that employers would have borne in the absence of a Medicare drug benefit, and they are made in addition to the \$71 billion in direct subsidy payments.

Summary of Basic Benefit Costs

CBO's estimate of overall costs per participant for the basic Medicare drug benefit reflected both the number of participants and average cost per participant in the two subsidy systems contained in the MMA (see Table 7). Average drug spending for participants in qualified employer and union drug plans was projected to be substantially higher than average spending for Part D enrollees (primarily reflecting differences in their projected spending under prior law), but Medicare's net payments were estimated to cover a smaller share of that spending. For all enrollees, the average net Medicare cost per participant is the weighted average of net costs for beneficiaries projected to receive coverage through a qualified employer or union plan and net costs for beneficiaries projected to enroll in Part D and receive coverage through a prescription drug plan or a Medicare Advantage drug plan.⁵⁰ As Table 7 indicates, the basic Medicare benefit is projected to pay for one-third of participants' covered drug spending, on average (once beneficiaries' premiums and plans' administrative costs are netted out). Combined, net federal payments to all of those plans will total \$448 billion over the fiscal year 2006-2013 period—which represents CBO's estimate of the net federal outlays involved in providing the basic Medicare drug benefit.

49. Increased Social Security payroll tax receipts, which are off-budget, would account for about \$2 billion of that total. The figures shown in Table 1 also include the estimated effect on revenues (an increase of \$0.2 billion over the 2004-2013 period) of the MMA's provisions that would modify the Hatch-Waxman Act. Those provisions would modestly reduce employers' drug costs, and CBO assumed that taxable compensation would increase slightly as a result.

50. With plans' administrative costs included, the net cost per participant for enrollees in prescription drug plans and Medicare Advantage drug plans is simply the gross cost per participant from Table 4 minus the average annual premium. When plans' administrative costs are excluded, the calculation is somewhat more complicated; in that case, the amount that is subtracted from gross benefit costs is only the portion of the average beneficiary premium that is attributable to those benefit costs. The differences between the gross amounts shown in Table 4 and the net amounts shown in Table 7 are thus slightly smaller when plans' administrative costs are excluded.

26 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table 7.****Estimated Spending by and Costs for Drug Benefit Participants, Calendar Years 2006 and 2013**

(Dollars)

	2006	2013
Participants in Qualified Employer and Union Drug Plans		
Number of participants (Millions)	8.2	9.5
Average drug spending by projected participants	3,815	6,689
Average Medicare costs per participant	766	1,369
Participants in Prescription Drug Plans and Medicare Advantage Drug Plans		
Number of participants (Millions)	29.0	33.9
Average drug spending by projected participants ^a	2,878	5,017
Average net Medicare costs per participant		
Excluding plans' administrative costs	1,104	1,913
Including plans' administrative costs ^a	1,221	2,021
All Participants		
Number of participants (Millions)	37.2	43.4
Average drug spending by projected participants	3,084	5,420
Average net Medicare costs per participant		
Excluding plans' administrative costs	1,029	1,795
Including plans' administrative costs	1,121	1,879
Memorandum:		
Medicare Enrollment (Millions)	42.6	49.6
Medicare Part B Enrollment (Millions)	39.9	46.6

Source: Congressional Budget Office.

Note: Average net subsidies reflect Medicare payments minus Part D premiums. Net figures that exclude plans' administrative costs equal gross benefit costs minus the portion of beneficiaries' premiums that is attributable to those benefit costs.

a. These figures differ from comparable figures that CBO released in November 2003 because of subsequent refinements in the calculation of spending and costs per participant that do not affect the cost estimate. See Congressional Budget Office, *Letter to the Honorable Don Nickles providing additional information about CBO's cost estimate for the conference agreement on H.R. 1* (November 2003).

Costs of the Low-Income Drug Subsidies and Effects on Medicaid and Other Direct Spending

The low-income drug subsidies provided under the MMA will total \$192 billion for fiscal years 2004 to 2013, CBO estimated. That figure includes spending under the transitional drug assistance program that will be in effect during fiscal years 2004 to 2006 as well as the costs of the additional low-income subsidies that will supplement the basic Medicare drug benefit starting on January 1, 2006. This section reviews the basis for those esti-

mates and also examines offsetting savings and costs for other federal programs—primarily Medicaid—that CBO estimated would result from the implementation of the MMA's drug benefit provisions.

Transitional Drug Assistance

Before the Medicare prescription drug program is implemented in 2006, a prescription drug discount card program will go into effect under the MMA. That program, which was designed to help participants obtain their prescriptions at reduced prices, will provide limited government subsidies to low-income beneficiaries. Specifically,

it will pay the enrollment fee (which cannot exceed \$30 per year) and cover up to \$600 in annual drug spending for Medicare beneficiaries with income below 135 percent of the federal poverty level who have no other form of drug coverage. Beneficiaries with income below the federal poverty level will be required to pay 5 percent of their drug costs; those with income between 100 percent and 135 percent of the federal poverty level will face a co-insurance rate of 10 percent.

About 15 percent of Medicare beneficiaries will be eligible for such transitional benefits under the MMA, CBO estimated, and about 20 percent of those eligible (or nearly 1 million individuals in 2005) will ultimately enroll. Participation was projected to be quite low because the discount card program will operate for only a short time (about 18 months) and will offer limited benefits.⁵¹ Combining the projected number of participants in the program and the cost per participant, CBO estimated that spending on transitional benefits would total about \$0.8 billion over the fiscal year 2004-2006 period. The bulk of that spending would occur in 2005.

Low-Income Drug Subsidies

In conjunction with the basic Medicare prescription drug benefit that begins in 2006, the MMA will cover some or all of the prescription drug premiums and required cost-sharing amounts for beneficiaries with low income and assets. Overall, the cost of providing those low-income subsidies would be \$191 billion over the 2006-2013 period, in CBO's estimation. That estimate was derived by projecting the number of beneficiaries who would be eligible for the subsidies, determining a participation rate for those beneficiaries, and multiplying the resulting number of participants by an estimate of their average subsidy costs.

Eligibility. The MMA will provide subsidies to two groups of individuals who are enrolled in the Medicare

drug benefit. The first group (which will be referred to here as eligible for "Subsidy A") consists of individuals with income below 135 percent of the poverty level and assets below \$6,000 for an individual or \$9,000 for a couple. That group also includes Medicare beneficiaries who receive full Medicaid benefits regardless of their income or assets. The second group (eligible for "Subsidy B") consists of all other individuals with income below 150 percent of the poverty level and assets below \$10,000 for an individual or \$20,000 for a couple. (All of those limits on assets will be adjusted for general inflation in later years.)

After analyzing data from Medicaid, the Medicare Current Beneficiary Survey, and the Census Bureau's Survey of Income and Program Participation, CBO estimated that about 35 percent of the enrollees in Medicare Part B—or about 14 million people in 2006, rising to 16 million by 2013—would be eligible for low-income subsidy benefits under the MMA (see Table 8).⁵² About 30 percent of those Medicare beneficiaries would be eligible for Subsidy A, with the other 5 percent qualifying for Subsidy B. Of the beneficiaries who would otherwise qualify for one of the subsidies in 2006, CBO estimated that about 1.8 million would be deemed ineligible on the basis of their assets.

Benefits. The MMA is slated to provide different benefits to the two groups of individuals described above.

Subsidy A. For individuals in this first group, the MMA will eliminate the basic drug benefit's deductible and will reduce other cost sharing to nominal amounts that will depend on income and whether a person is a dual eligible. For all enrollees in this group, those nominal copayments will apply to all spending below the catastrophic threshold, thus filling in the doughnut hole in the standard Medicare drug benefit. Dual eligibles residing in nursing homes will not face any cost sharing, whereas other dual eligibles with income below the poverty level will pay \$1 for a generic drug or preferred brand-name drug with a generic competitor and \$3 for other covered drugs in 2006 (those amounts will be indexed to general inflation in later years). Other enrollees in Subsidy A will

51. CBO did not have to make an assumption about enrollment in the prescription drug discount card program as a whole because that factor did not affect the estimate of mandatory outlays. Even so, the experience of the drug discount card program to date may not be indicative of the full drug benefit's likely prospects, for two reasons. First, although a large number of card sponsors are participating in the discount card program, that program does not require sponsors to bear much financial risk. Second, eligible beneficiaries may not be strongly motivated to enroll in the program because of its limited benefits and temporary nature.

52. For reasons discussed above in the section on enrollment in the basic drug benefit, CBO based its estimates of participation on the number of Medicare beneficiaries who had chosen to enroll in Part B of Medicare.

28 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table 8.****Number of Enrollees in Medicare Part B Who Are Eligible for Low-Income Drug Subsidies in Calendar Year 2006**

(Millions of enrollees)

	Income as a Percentage of the Federal Poverty Level							Total
	Below 100	100- 120	120- 135	135- 150	150- 175	175- 200	Above 200	
Beneficiaries Eligible for Subsidy A								
Dual eligibles	4.4	0.9	0.2	0.2	0.2	0.1	0.3	6.4
Other beneficiaries	<u>2.8</u>	<u>2.1</u>	<u>1.1</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>5.9</u>
Subtotal	7.1	3.0	1.4	0.2	0.2	0.1	0.3	12.3
Beneficiaries Eligible for Subsidy B	<u>0.2</u>	<u>0.3</u>	<u>0.2</u>	<u>1.2</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>1.9</u>
Total Eligible Beneficiaries	7.4	3.2	1.6	1.4	0.2	0.1	0.3	14.2
Beneficiaries Not Eligible for Subsidies	<u>0.4</u>	<u>0.4</u>	<u>0.5</u>	<u>0.5</u>	<u>2.4</u>	<u>2.4</u>	<u>19.2</u>	<u>25.7</u>
Total Medicare Part B Enrollment	7.8	3.7	2.1	1.8	2.6	2.5	19.5	39.9

Source: Congressional Budget Office.

Notes: Some of the figures in this table differ slightly from comparable figures CBO released in November 2003 because of the correction of a calculation error not affecting the cost estimate. See Congressional Budget Office, *Letter to the Honorable Don Nickles providing additional information about CBO's cost estimate for the conference agreement on H.R. 1* (November 2003).

See the text for an explanation of Subsidies A and B.

pay either \$2 or \$5 per prescription in 2006, with those amounts increased each year at the projected rate of growth in per capita drug expenditures for the Medicare population. Once any of those beneficiaries reaches the Medicare benefit's catastrophic threshold (\$5,100 in total covered drug spending in 2006), they will be not liable for any further cost sharing. And depending on which drug plan they join, they will pay either no premium or a reduced premium.⁵³

53. For beneficiaries in this group, a full premium subsidy is provided up to the national average premium. Beneficiaries who join a more expensive drug plan will thus pay the difference between that plan's premium and the national average. (If no plan is available in an area for a premium at or below the national average, the subsidy will fully cover the premium for the lowest-cost plan in that area, with beneficiaries paying the difference to join another plan.) In that system, subsidized beneficiaries would have an incentive to join plans with premiums close to the national average, but CBO assumed that some of them would join plans costing less than that average. As a result, the average payment for premium subsidies for this group was projected to be slightly below the national average premium amount.

Subsidy B. For individuals in this second group, the subsidy will lower the basic benefit's deductible (to \$50 in 2006) and will limit cost sharing to 15 percent for all other spending below the catastrophic threshold. Beneficiaries' cost sharing for spending above that threshold will equal \$2 or \$5 in 2006 (depending on the type of drug purchased), and those amounts as well as the deductible will be indexed to growth in per capita drug expenditures for the Medicare population. Beneficiaries also will receive the same premium subsidy as the first group if their income is less than or equal to 135 percent of the poverty level, with the premium subsidy declining to zero for individuals with income equal to 150 percent of the poverty level. (Beneficiaries with income below 135 percent of the poverty level can be in this group if they are not dual eligibles and their assets are too high to qualify for the substantially higher subsidy.)

Participation. CBO projected that all dual-eligible beneficiaries would participate in the low-income drug subsidy program but that a significant proportion of the remaining eligible population would not apply for those

subsidies. For those beneficiaries, CBO's estimate of the number of people who would enroll was based on several factors, including the value of the subsidies and historical participation in the qualified Medicare beneficiary (QMB) and specified low-income Medicare beneficiary (SLMB) programs. (Those programs pay some or all of the premiums and cost sharing under Parts A and B of Medicare for beneficiaries with income below 120 percent of the poverty level and limited assets.) In those programs, many beneficiaries who are eligible do not enroll. Specifically, about one-third of eligible beneficiaries are currently estimated to enroll in the QMB program, which covers Medicare's premiums and all cost-sharing requirements (and thus is projected to have an average value of nearly \$3,000 for participants in 2006). The take-up rate for the SLMB program, which covers the Part B premium and thus would be worth about \$900 to each enrollee in 2006, is approximately 13 percent.⁵⁴

CBO also estimated that the share of eligible beneficiaries receiving low-income subsidies would rise gradually after the implementation of the Medicare drug benefit. (Unlike the basic drug benefit, which penalizes individuals for late enrollment, the additional low-income subsidies are available to Part D enrollees at any time and with no penalty.) For 2006, CBO projected that there would be about 8.7 million recipients of the low-income subsidies, or about 60 percent of those eligible. Ultimately, CBO assumed, almost 70 percent of those eligible would receive low-income subsidies under the MMA, which translates into 11.2 million enrollees in 2013. About 75 percent of those eligible for the substantially higher subsidy would ultimately receive it, while about 35 percent of those eligible for the somewhat higher subsidy would receive that benefit. Participation rates for the substantially higher subsidy program would be much greater because they would include all dual eligibles—about 6.4 million individuals in 2006, rising to 7.4 million by 2013. Excluding dual eligibles, about 45 percent of eligible beneficiaries would ultimately enroll in the low-income subsidy program, CBO assumed. Although the average value of the low-income drug subsidy would be somewhat lower than the savings typically available

through the QMB program, CBO assumed that participation in the low-income drug subsidy program would be somewhat greater than that for other welfare-related programs because individuals are allowed to enroll at offices of the Social Security Administration—which is easier for enrollees and carries less stigma.

Costs per Participant. In estimating the costs of the subsidy payments per participant, CBO started with the average cost-sharing liabilities that those beneficiaries would incur under the standard Medicare benefit. (That calculation as well as the average cost of providing the standard benefit took into account any increase in drug use that would occur for beneficiaries newly receiving the relatively generous coverage provided by the low-income drug subsidies.) Those averages were then adjusted to reflect the assumption that Medicare beneficiaries who chose to enroll would generally have higher average drug costs than beneficiaries who were eligible for those subsidies but chose not to participate—that is, that some adverse selection would occur because those with the highest drug costs would gain the most by enrolling. In part as a result of that adverse selection, the difference between the average cost of providing the two types of benefits outlined above would be relatively small despite the differences in their overall generosity, CBO estimated. For 2006, average payments for cost sharing were estimated to be about \$1,400 for beneficiaries in the first group (Subsidy A), rising to about \$2,500 in 2013; for the second group (Subsidy B), average payments for cost sharing would climb from roughly \$1,300 in 2006 to about \$2,300 in 2013. (Under the MMA, drug plans would be reimbursed for those expenses on a cost basis.) Average premium payments made on behalf of enrollees would also be somewhat greater for the first group owing to the substantially higher premium subsidy (with a maximum value of \$418 in 2006 and \$692 in 2013, according to CBO's estimates of average premiums).

Interactions with Medicaid

Because of the large number of low-income Medicare beneficiaries who are enrolled in or eligible for various benefits through the Medicaid program, the Medicare drug benefit and low-income drug subsidies also have substantial implications for Medicaid spending on behalf of those beneficiaries—including but not limited to drug spending. Those implications, along with an additional provision of the MMA, not only affect federal spending but also have important impacts on states' Medicaid costs.

54. Those participation rates exclude beneficiaries who are also eligible for full Medicaid benefits. Those beneficiaries receive more benefits and have higher take-up rates than beneficiaries not dually eligible and were assumed to enroll in the low-income drug subsidy program.

30 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

Federal Drug Spending Under Medicaid. CBO estimated that under prior law, about 7.5 million Medicare beneficiaries would have had some type of drug coverage through Medicaid in 2006. (That figure is higher than the number of dual eligibles given above because it includes beneficiaries who would have received limited drug coverage through special Medicaid waiver programs.) Because the MMA will replace Medicaid's coverage for prescription drugs for individuals who enroll in the Medicare drug benefit, it will lead to substantial savings in the Medicaid program. By formula, those savings will be split between the federal government and the states at the regular federal matching rate (57 percent, on average).

CBO estimated that direct federal spending on prescription drugs by Medicaid would decline by \$152 billion under the MMA over the 2006-2013 period. As part of its estimate, CBO assumed that states currently providing limited drug coverage to certain Medicare beneficiaries through special Medicaid waiver programs would discontinue those programs and instead provide coverage using state funds only. States will have a strong incentive to do so because spending by state pharmacy programs counts toward the catastrophic threshold in the Medicare drug benefit, whereas Medicaid spending does not (and, indeed, federal matching funds would not be allowed for purposes of supplementing the Part D benefit). CBO's estimate of federal Medicaid spending under prior law included \$18 billion in costs related to those special waiver programs for the 2006-2013 period. As a result of the MMA, CBO assumed that that spending would cease (with the resulting savings included in the \$152 billion estimate).

Other Federal Medicaid Costs. The prescription drug benefit and low-income subsidy programs would affect Medicaid spending in several other ways. In particular, CBO estimated that the MMA would cause an increase in Medicaid spending for individuals newly enrolled in the QMB and SLMB programs. Because that additional enrollment would be induced by the drug benefit's new low-income subsidies, CBO attributed those costs to the MMA's drug benefit provisions.

By 2013, about 1.3 million beneficiaries enrolled in the low-income drug subsidy program would also become new enrollees in some form of Medicaid coverage, in CBO's estimation. For all of those beneficiaries, Medicaid would pay their Medicare Part B premium. About half of

those beneficiaries would also qualify for and enroll in Medicaid coverage of all cost-sharing obligations under Medicare (through the QMB program). That coverage would generate direct costs for Medicaid of about \$900 per enrollee.⁵⁵ A small share of the new QMB participants (roughly 100,000 individuals) would also qualify for full Medicaid benefits, at an additional cost of about \$900 per person in 2013. CBO assumed that coverage for those new dual eligibles would, on average, be much less costly than coverage for current dual eligibles—particularly for nursing home care, because beneficiaries who could have qualified for Medicaid coverage of their nursing home costs would almost certainly be enrolled in the program already. Of the total costs incurred by Medicaid, about 57 percent would represent federal spending.

Medicaid would incur additional costs to provide prescription drug benefits to its non-Medicare populations, CBO estimated. Such costs would rise slightly over the budget window because the advent of Medicare prescription drug coverage would increase demand for prescription drugs and thus have a price effect, as discussed above. There would also be additional spending for the administrative costs to states' Medicaid programs for the low-income subsidy program. (Medicaid's administrative costs are counted as direct spending.) In total, those other effects would cost the federal government \$10 billion through 2013, CBO estimated. Combined with the estimate of \$152 billion in federal savings on Medicaid drug costs, that \$10 billion in costs would yield a net estimate of \$142 billion in federal Medicaid savings over that period (see Table 1 on page 2).

Reduction in Federal Medicaid Payments. Under the MMA, the federal government would also recover some of the savings that states would otherwise realize in their Medicaid programs from having dual eligibles covered by the Medicare prescription drug benefit and low-income

55. The costs of providing QMB benefits are somewhat lower than the savings that enrollees see because costs are based on Medicaid's payment rates, which are often lower than Medicare's payment rates. CBO also assumed that full coverage of Medicare's cost-sharing liabilities would lead enrollees to use more Medicare services, increasing Medicare's costs by about \$1,000 for each of those beneficiaries in 2013. In the figures provided here, however, the effects of the interaction between Part D and Medicare spending for benefits under Parts A and B were included in the estimated cost for the MMA's other provisions rather than in the estimated cost for the drug benefit provisions.

Table 9.**Impact of the Medicare Prescription Drug Benefit on States' Medicaid Outlays, Fiscal Years 2004 to 2013**

(Billions of dollars)

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total, 2004- 2008	Total, 2004- 2013
Spending for Prescription Drugs	0	0	- 5.2	- 11.2	- 12.4	- 13.8	- 15.3	- 16.9	- 18.8	- 20.9	- 28.9	- 114.6
Spending for Newly Enrolled Dual Eligibles, QMBs, and SLMBs	0	0.1	0.2	0.5	0.6	0.7	0.8	0.9	0.9	1.0	1.5	5.8
Reduction in Federal Medicaid Payments ("Clawback" Mechanism)	0	0	5.7	9.1	10.0	10.8	11.7	12.6	13.7	14.9	24.8	88.5
Administrative Costs and Other Spending	<u>0.1</u>	<u>0.1</u>	<u>0.3</u>	<u>0.3</u>	<u>0.3</u>	<u>0.3</u>	<u>0.4</u>	<u>0.4</u>	<u>0.4</u>	<u>0.5</u>	<u>1.1</u>	<u>3.1</u>
Total	0.1	0.2	0.9	- 1.3	- 1.5	- 1.9	- 2.4	- 3.1	- 3.7	- 4.4	- 1.5	- 17.2

Source: Congressional Budget Office.

Notes: Estimates do not include the effects of the Medicaid provisions in Title X of the Medicare Modernization Act or the effects of the prescription drug benefit on other state spending.

QMB=qualified Medicare beneficiary; SLMB =specified low-income Medicare beneficiary.

drug subsidies. (That provision in the law is often referred to as the "clawback" mechanism.) Starting in January 2006, each state will make a monthly payment equal to one-twelfth of the product of the following factors:

- Average per capita spending by Medicaid on prescription drugs for dual eligibles in that state in 2003 (adjusted to the current year using a national average growth rate for drug spending);
- The state's Medicaid matching rate;
- The number of dual eligibles in the state; and
- A percentage specified by the law that will equal 90 percent in 2006, gradually decline to 75 percent by 2015, and remain constant after that.

Those payments will total \$88 billion over the 2006-2013 period, CBO estimated. Under the MMA, the payments will be credited to the new Medicare prescription drug account in the Part B trust fund.

Impact on States' Medicaid Costs. CBO estimated that, on net, states' Medicaid programs as a group would save \$17 billion through 2013 as a result of the MMA's drug benefit provisions (see Table 9). Savings for individual states may not be proportional to the overall amount, but CBO did not estimate effects for individual states. States would save \$115 billion in prescription drug costs through 2013, an amount that corresponds to the \$152 billion in federal savings on Medicaid drug costs discussed above. (That is, total savings to the Medicaid program were projected to be \$267 billion, of which the states' share would be 43 percent, or \$115 billion.) Similarly, the spending for new enrollees and administrative costs shown in Table 9 represents states' shares of payments that generated those \$10 billion in federal costs. The figures in Table 9 are for Medicaid outlays only and do not include any estimate of the impact of the drug benefit on other state expenditures. (For example, a portion of the federal subsidies to former employers providing drug coverage to their retirees would go to the states that are a source of retiree drug coverage for Medicare beneficiaries today.)

32 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Other Effects on Direct Spending**

Effects on Outlays for Federal Retirees. Some federal retirees would enroll in a Medicare drug plan, CBO estimated, in which case that plan would pay first for their drugs and then their current health plan would supplement that coverage. As a result, a portion of their prescription drug costs would be indirectly shifted to Medicare (that portion is included in the costs of providing the Medicare benefit). CBO's estimate reflected that impact, as well as small effects on other federal programs that pay for prescription drugs, and showed the Medicare law's drug benefit provisions as reducing mandatory federal spending by about \$3 billion through 2013. However, the MMA also provided \$1.5 billion in mandatory spending for the federal administrative costs of implementing the drug benefit in 2004 and 2005, so the net impact on other direct spending would be a reduction of \$1.5 billion over 10 years. CBO did not estimate whether federal retirees would generate payments under the employer subsidy system because even if they did, those payments would be considered intragovernmental transfers and would not count as outlays.

Other Effects on Medicare Outlays. Adding a prescription drug benefit to Medicare could also have ripple effects on the rest of the program, but little conclusive evidence exists as to the expected direction or magnitude of those effects. For some seniors, greater access to outpatient prescription drugs would improve their health, reducing their use of hospitals and other services that Medicare now covers under Parts A and B. For other seniors, however, use of health care would increase. For example, using a greater number of drugs raises the probability of adverse events—such as harmful drug interactions or side effects—that could lead to new or longer visits to hospitals, emergency rooms, and other health care providers. While such adverse reactions would probably be impossible to prevent altogether, Medicare spending could increase even without them as beneficiaries used more ancillary services (such as additional lab tests) in conjunction with their drug treatment regimens. As discussed above, however, the MMA's net impact on drug use is likely to be modest; in part, that is because many beneficiaries already have some form of coverage for their drug costs, and in part because beneficiaries with no drug coverage nonetheless fill a substantial number of prescriptions. Overall, CBO assumed that costs for other Medicare services would not change significantly because of the drug benefit.⁵⁶

Another aspect of Medicare that could be affected by the availability of a drug benefit is the rate of participation in integrated private health plans—which could in turn have an important impact on spending under Part C for Medicare's other benefits. Those pressures would go in conflicting directions, however. On the one hand, the managed care plans that take part in Medicare have historically attracted beneficiaries by offering benefits beyond the basic Medicare package—the most desirable of which has been prescription drug coverage. Once drug coverage became available to beneficiaries in the traditional fee-for-service Medicare program, such plans might lose one of their principal competitive advantages. That effect would be muted, though, to the extent that the Medicare beneficiaries remaining in private health plans today did so for reasons other than drug coverage. Also, the scope of that drug coverage has declined substantially in recent years.⁵⁷ Instead, those enrollees might be attracted by the coverage of Medicare's cost sharing that private health plans typically provide or by other, extra benefits they offer (which would largely continue).

On the other hand, integrated private plans that offered drug coverage would now be paid for the value of that coverage, rather than having to finance it from what they save in providing (relative to the statutory payment rate) Medicare's other benefits. Private health plans would thus be able to use a portion of those savings to give beneficiaries partial rebates on their Part B or Part D premiums or to provide additional benefits. By offering a more integrated delivery system, such private plans might also be able to provide a slightly less restrictive benefit for the same cost as that offered by a stand-alone prescription drug plan (they could have fewer limits on the drugs included in their formulary, for instance) so as to attract enrollees. On balance, then, CBO assumed that adding a drug benefit under the MMA would neither increase nor decrease enrollment in Medicare's private health plans.

56. For a more detailed discussion of the potential effects of drug coverage on the use of other health services, see Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare*, pp. 31-34 and 49-52.

57. See Lori Achman and Marsha Gold, *Trends in Medicare+Choice Benefits and Premiums, 1999-2002* (report prepared by Mathematica Policy Research for the Commonwealth Fund, November 2002).

Uncertainty and Conclusions

It is always difficult to predict the outcome when a complex and substantially new program is created, particularly in the case of an entitlement program with a large number of potential enrollees. Actual program costs for the Medicare drug benefit could differ from CBO's projections, for several reasons.

- Current drug spending by the Medicare population and its future rate of increase could be higher or lower than CBO estimated;
- The take-up rate among eligible beneficiaries for the basic drug benefit could be higher or lower than CBO projected (with the impact on costs depending significantly on whether those who declined coverage were representative of the Medicare population);
- Risk-bearing private drug plans could have more difficulty forming than CBO assumed, or, alternatively, they could succeed in limiting drug costs to a greater extent;
- The rate at which employers dropped retiree drug coverage could differ from CBO's projections;
- Beneficiaries' enrollment in the low-income subsidy program or the costs of those subsidies per enrollee could exceed or fall short of CBO's estimates;
- The impact on federal Medicaid spending (relative to the amounts that would have been spent without the MMA) could be larger or smaller than CBO anticipated; and
- CMS, in promulgating regulations to implement the program, could interpret the law in ways that differ from the assumptions used by CBO in estimating its costs.

As a result of such differences, the actual number of participants and the average cost per participant could vary—in either direction—from CBO's projections.⁵⁸ Until such information becomes available, the cost estimate presented here represents the agency's best judgment about the net budgetary impact of the Medicare drug benefit that was established by the MMA.

58. For a discussion and explanation of the main differences between CBO's cost estimate for the MMA and the estimate developed by CMS, see the statement of Douglas Holtz-Eakin, March 24, 2004.

APPENDIX

The Drug Benefit's Risk Corridor System

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a system of “risk corridors” for prescription drug plans and Medicare Advantage drug plans. That system would limit to some extent the profits or losses those plans would incur if their costs of providing the basic Medicare drug benefit turned out to be lower or higher than they had estimated in their bid submission. The system would work in the following way. At the end of the calendar year, the Department of Health and Human Services (HHS) would compare each plan’s expected and actual benefit costs (excluding federal reinsurance payments and administrative costs). Drug plans incurring benefit costs that exceeded their expected levels by a sufficient degree would then be partially compensated by additional federal payments, whereas drug plans with benefit costs that fell far enough below their expectations would generally have to reimburse Medicare at the same rate. (Because plans’ expected costs would determine the total amount they were paid up front, the risk corridor system also would help keep payments in line with actual costs while giving plans a residual incentive to control those costs.)

The thresholds for triggering risk corridor payments and the share of the difference between actual and expected costs that those payments covered would vary under the statute.

- For 2006 and 2007, drug plans would bear all gains and losses that fell within 2.5 percent of their expected costs. If costs differed from expectations by more than 2.5 percent but less than 5 percent, the risk corridor payment would cover 75 percent of the amount in that range. If actual and expected costs differed by more than 5 percent, the risk corridor payment would cover 75 percent of the amount between 2.5 percent and 5 percent, and 80 percent of the amount in excess of 5 percent. In addition, if a sufficient number of plans serving a substantial majority of enrollees received risk corridor payments for the year, then the

MMA would increase the share of costs covered in the initial range from 75 percent to 90 percent for that year.

- For the 2008-2011 period, plans would face more risk as the risk corridor thresholds doubled—from 2.5 percent to 5 percent and from 5 percent to 10 percent, respectively—and the share of costs covered by the risk corridor payment in the initial range dropped from 75 percent to 50 percent (with no provision for a higher rate if most plans missed their targets). Above the second threshold (that is, for deviations exceeding 10 percent), the payment rate would remain at 80 percent.
- After 2011, HHS could increase the first threshold above 5 percent and the second threshold above 10 percent.

The corridors would be structured symmetrically. Thus, a plan whose costs exceeded the expected level by 10 percent would receive a risk corridor payment *from* Medicare, but that plan would have to pay the same amount *to* the government if its costs fell below expectations by 10 percent.

How the Risk Corridor System Would Work: An Illustrative Example

The effects of the MMA’s risk corridor system can be illustrated using three hypothetical drug plans in 2006 with the same expected benefit costs but differing actual benefit costs in 2006 (see Table A-1). To keep the example relatively simple, costs and payments are expressed as per-enrollee averages, and the reinsurance payments are assumed to cover exactly one-third of total benefit costs in all three plans (both in expectation and in actuality). In the example, the costs for covered benefits in Plan 1 fall below the expected level by \$75 per enrollee. By assump-

36 A DETAILED DESCRIPTION OF CBO'S COST ESTIMATE FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT**Table A-1.****Example of How the Drug Benefit's Risk Corridors Would Operate in 2006**

(Average amount in dollars per enrollee per year)

	Plan 1	Plan 2	Plan 3
Expected Benefit Costs	1,500	1,500	1,500
Expected Federal Reinsurance Payments	<u>500</u>	<u>500</u>	<u>500</u>
Net Expected Benefit Costs	1,000	1,000	1,000
Actual Benefit Costs	1,425	1,485	1,650
Actual Federal Reinsurance Payments	<u>475</u>	<u>495</u>	<u>550</u>
Net Actual Benefit Costs	950	990	1,100
Initial Gain (+) or Loss (-)	50	10	-100
Risk Corridor Payment to Plan (+) or from Plan (-)			
For costs between 2.5 percent and 5 percent	-18.75	0	18.75
For costs above 5 percent	<u>0</u>	<u>0</u>	<u>40.00</u>
Total	-18.75	0	58.75
Final Gain or Loss	31.25	10.00	-41.25
Memorandum:			
Percentage Difference Between Expected Benefit Costs and Actual Benefit Costs	5	1	-10

Source: Congressional Budget Office.

Note: The examples used here assume that the test for triggering a higher payment rate in the initial range (between 2.5 percent and 5 percent) is not met. They also ignore any effects of risk adjustment.

tion, one-third of that difference is effectively recouped via a lower-than-anticipated reinsurance payment from the government. In the absence of any risk corridor provisions, Plan 1 would have seen a gain of \$50 per enrollee (beyond any normal profits it had built into its bid submission). But because that gain constitutes more than 2.5 percent of its expected benefit costs (net of individual reinsurance), it must make a risk corridor payment to Medicare of \$18.75 per enrollee (75 percent of the amount by which its gain exceeds \$25). Its final gain is thus reduced to \$31.25 per person.

Plan 2 also experiences a small gain in this example, but because that gain represents only 1 percent of its expected net costs, it does not have to make a risk corridor payment. By contrast, Plan 3 incurs total benefit costs of \$150 per enrollee more than it had anticipated; although a portion of that excess is covered by greater-than-expected federal reinsurance payments, that plan would (but for the risk corridors) face a loss of \$100 per person.

The risk corridor payment from Medicare covers nearly 60 percent of Plan 3's remaining losses, though, reducing its actual net loss to \$41.25 per enrollee.

Risk Corridors and the MMA's Other Risk-Mitigation Measures

The MMA incorporates three methods of risk mitigation: risk corridor payments, federal reinsurance payments, and a risk adjustment. Although they have some similarities, each method would address somewhat different risks in somewhat different ways.

Risk adjustment would account for differences in beneficiaries' expected drug spending based on their health status or other individual factors. HHS would thus pay more to plans with sicker enrollees (who would be expected to incur higher drug costs) and less to plans with healthier enrollees. Those payment adjustments would be made prospectively. If designed well, the risk-adjustment

system would vary payments to take into account factors that predictably affected an individual's future drug use but that were beyond the control of a drug plan. Therefore, it would be targeted primarily at plans' risk of experiencing adverse selection and would not address other sources of financial risk. For example, if drug costs generally turned out to be higher in a given year than had been expected, risk adjustment of Medicare's payments would not offset the resulting higher costs. By the same token, if a risk-adjustment system was truly prospective over time—and the adjustment made for an individual did not depend on steps taken by his or her plan, such as the number or type of prescriptions that the plan had approved—it could keep payments in line with costs without distorting plans' incentives to control those costs. (By adjusting federal subsidies, it would also help keep beneficiaries from paying higher premiums simply because they joined a plan with sicker enrollees.) Even so, trade-offs could arise between assuring payment accuracy in the short run and encouraging cost control in the longer term.

Federal reinsurance payments would be made retrospectively on the basis of actual drug spending for individuals who reached the drug benefit's catastrophic threshold. Those payments would limit the risk that plans faced in attracting the highest-cost enrollees but would not address the financial risks involved in providing the front-end portion of the benefit. Reinsurance payments would also provide some protection against general uncertainty about future drug costs—because if average drug prices or utilization was higher or lower than expected, the costs of providing benefits above the catastrophic threshold would probably vary in a corresponding manner. If overall drug costs proved to be lower than projected, the reinsurance payment system would also allow the government to share in the savings.

Risk corridor payments would also be made retrospectively (and would be applied after risk adjustment and federal reinsurance payments), but they would limit more directly the overall level of profits or losses that a drug plan experienced. As structured in the MMA, the risk corridors would provide plans with strong incentives to control costs below the first risk corridor threshold but then generally would share more risk the greater the deviation between actual and expected costs—perhaps reflecting the assumption that deviations of such magnitude would have to result from forces beyond the plan's control. Thus, the risk corridors would primarily protect against large shocks in drug spending growth rates and against

misestimates of average drug costs per enrollee (particularly in the initial years of the benefit, when uncertainty about that average would be greatest and when the risk corridors were narrower). Risk corridor payments would address the risks of favorable or adverse selection only in the event that risk adjustment of payments did not account well for the variation in plans' costs for providing the front-end portion of the benefit—and even then the residual deviation between actual and expected costs would have to be rather large before risk corridor payments kicked in.

The Impact of Risk Corridors on Program Costs

In principle, the expected value of risk corridor payments would be zero. As discussed in the body of this report, drug plans would have strong incentives to submit accurate bids (in part because they would be reviewed by HHS). On average, cost overruns by some plans or in some years would thus offset lower-than-expected costs by other plans or in other years. In practice, however, the Congressional Budget Office (CBO) assumed that plans would be slightly more likely to reveal losses than gains under the risk corridor system and that HHS would not be able to audit costs perfectly (given the potential for reasonable differences in interpretation about which benefit costs were allowable and which were administrative).¹

The risk corridor system mainly affected CBO's estimate of program costs through its impact on plans' incentives to control costs. Precisely because plans would be partially insulated from any resulting losses and would reap only a portion of any resulting gains, CBO assumed that they would be somewhat less aggressive in managing drug costs. To quantify that effect, CBO modeled the impact of the risk corridor system on the variability of plans' net costs. Among other factors, that modeling took into account the number of regions that might be established for drug plans to serve, because variability in costs is a function of plan size and average plan size depends in turn on the number of regions. Overall, CBO concluded that the risk corridor provisions specified in the MMA would yield a modest increase in the costs of providing the Medicare drug benefit (but primarily in the initial years of the benefit, when the corridors were relatively narrow).

1. CBO also assumed that drug plans bearing less risk would have lower administrative costs, so the MMA's risk corridor system somewhat reduced the agency's estimate of those costs.

